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ABSTRACT

The conference papers, workshop committee reports and records of panel discussions are presented in this proceedings. The contents are separated into the following sections: (1) General Sessions which includes papers on information systems in the pharmacist's modern role and on system design considerations; (2) Workshops, committee reports and the round-table; (3) Conference summary and (4) Selected papers concerning Federal agency systems and system concepts. The appendices contain: the post-conference questionnaire, conference staff and registrants, and communications. (Author/NH)

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PROCEEDINGS

COMPUTER-BASED INFORMATION SYSTEMS IN THE PRACTICE OF PHARMACY

July 19-21, 1971

Sponsored by
School of Pharmacy
University of North Carolina
at
Chapel Hill

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The National Pharmaceutical Council

Paul D. Olejar
Editor

LI 003 570

FOREWORD

The School of Pharmacy of the University of North Carolina was honored to sponsor the Conference on Computer-Based Information Systems in the Practice of Pharmacy. Some 180 persons registered from thirty states. They represented a wide range of interests and activities relating to health care and information services. Almost thirty percent of those polled replied to a post-conference questionnaire. They agreed that the Conference served a greatly needed function in providing a means of communication between the diverse groups that have an interest and responsibility in this area, and in helping to throw light on the variety of activities now going on and the complexity of the challenges that must be faced.

The papers, workshop committee reports, and records of panel discussions are presented, therefore, in the hope that this compilation will be beneficial as a reference.

In behalf of the School of Pharmacy, I offer my thanks and appreciation to the many individuals, organizations and agencies responsible for the success of this program. There were many. I especially want to express appreciation to the National Pharmaceutical Council for its generous financial support which made the Conference possible, and to the Planning Committee that met in February and demonstrated the need for this meeting.

George P. Hager, Dean
School of Pharmacy
University of North Carolina

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I. GENERAL SESSIONS

INTRODUCTION

George P. Hager, Ph.D.
Dean, School of Pharmacy

It is a great pleasure to welcome you to the Conference on Computer-Based Information Systems in the Practice of Pharmacy.

I expect Dr. Cecil G. Sheps, our Vice Chancellor for Health Sciences, to open the Conference. At this time, I think that we might start off by referring to the recent report of the Task Force on the Pharmacist's Clinical Role from the National Center for Health Services Research and Development. This report represents the deliberations of a committee operating under Dr. Donald C. Brodie, who is with us this morning. With his permission, I will quote part of it.

> "The pharmacist is a health resource whose potential contribution to patient care and public health is grossly underdeveloped and which, thereby, is used ineffectively. In order to initiate an appraisal of potential and emerging roles of the pharmacist, the University of California School of Pharmacy and the National Center for Health Services Research and Development co-sponsored an interdisciplinary Conference on Pharmacy Manpower in September, 1970. A 'clinical' role prompted the greatest apparent interest and enthusiasm among the participants, although this role, as yet, lacks precise definition. Included in the results of the Conference were three mandates calling for: (1) the development of a set of working criteria for a clinical role, (2) a demonstration of the role-effectiveness, and (3) a determination of cost effectiveness."

An arbitrary classification was used in arranging the functions of the pharmacist that relate to this clinical role. All we have here are bare titles. They can be grossly misleading but each one of you will receive a copy of the task force report. You already have in the material handed to you a copy of the "Pharmacy in the 70's" Conference in California last September. I do hope that you will read it and think during this meeting about this clinical role of the pharmacist. The functions as listed in the report are as follows:

"A. Prescribing Drugs.
B. Dispensing and Administering Drugs.
C. Documenting Professional Activities.

D. Direct Patient Involvement.
E. Reviewing Drug Utilization.
F. Education, (i.e. objectively used here, education of patients and public, etc. by the pharmacist.)
G. Consultation. (This function deals with the physician, the patient, and the community.)"

I think there is no question that the pharmacist is a major switching point in the information transfer chain that is required for the rational, safe and effective use of drugs in health care. This is a bold and brave statement. It is a very significant and important claim, and it is also very real. The pharmacist is a major switching point in this information transfer chain and must be most effective in that role for the rational, safe and effective use of drugs in health care. From the standpoint of health care, this is a most important consideration. A computer-based storage, analysis, and retrieval system operating in a network that involves all pharmacies is to the pharmacist's intellectual processes in his clinical role as the microscope is to the eye.

I wish that we would accept, or during our conference somehow reinforce a basic thesis, one which has been discussed for more than a year with a number of people and probably before that, too. I am speaking only personally because it was my pleasure to talk with Dr. T. Donald Rucker at Williamsburg at the National Association of Chain Drug Stores meeting last Fall, when this point was brought out. Don can speak for himself on this point, but as a basic premise, it is this: a computer-based network for the practice of pharmacy is sine quo non for the economic administration of third party payment programs in the future. If this were the only raison d'etre for a computer-based information system, this alone would justify it. A computer-based information network in the practice of pharmacy is indispensable for the economic administration of third party payment programs in the future. Otherwise we can anticipate the serious problem that would result when administrative costs would exceed the cost of medications and the services related to their proper distribution. In effect, the tail would wag the dog. We simply would be adding to medical care and health care costs.

The tail truly can wag the dog unless we do look forward to procedures which will keep these things in proper perspective. So, as a basic thesis, a computer-based network for the practice of pharmacy is indispensable for the economic administration of the third party payment programs in the future.

But there are many possible bonuses. If, at this time, we look far enough down the road and plan properly, other purposes in addition to third payment administration, could be served, using the same hardware, the same network, and gaining more dividends from such an investment. Now, what else could be accomplished by such a network? It is the purpose of this conference -- the primary purpose -- to do some forward looking so as to discern these other things which can be achieved and to gain some impression of their order of priority. For example, the fiscal operations of the pharmacist could be assisted. Such a system could take care of his accounts receivable and his inventory control, perhaps direct automatic reordering, and so on. Many of his fiscal operations, which are burdensome things in the multiple small transactions that are involved in the practice of pharmacy, could be economically and conveniently handled for the pharmacist by a computer-based system so that he could then get on with his professional function.

In another context such a system could also provide much with regard to the application of the very large bank of pharmaceutical information which is also at the same time highly dynamic, but also very relevant to patient care. For example, the patient medication records that are maintained by the pharmacists could be very conveniently compiled through such a system. Moreover, the medication that these patients are receiving from a variety of sources could be compiled at the same point of the table, and could be called out by a physician, for example, when there is an episode where he seriously needs some knowledge of what the patient has been taking at various points in time, or over a period of time. Patient medication records and drug abuse control information are the kind of information that could be conveniently put into the system in order, for example, to discern the outlet through which is flowing an inordinate amount of dangerous substances. Or the system could help to identify that individual who is shopping from store to store and town to town in order to accumulate a gallon of paragoric, if you wish, or other controlled substances in order to indulge in an abusive use thereof. Adverse reaction reports also could be greatly expedited by such a system. I am sure that the people here from the Food and Drug Administration are very sensitive to the obstacles to convenient and speedy adverse reaction reporting. The application of drug-drug interaction information, especially in this day where patients are receiving many different drugs at the same time, very often prescribed by different physicians, and much other information of this type will be discussed at one of the workshops.

Another area of drug utilization deals with the question of whether the written prescription is actually filled. We suspect that in many cases there is much effort invested in diagnosis and much judgment on the part of the physician in prescribing medication, but the prescription is never filled, nor taken, and the health care process breaks down accordingly. In addition, there is the subject of counterfeiting of prescriptions. Can prescription orders somehow be authenticated through a system of this type? Can the pharmacist be alerted regarding prescription order refills in accordance with the physician's intention? Is the patient using a month's supply in a week or a week's supply in a month, and has the time come for him to refill it if he is taking the drug according to the physician's directions? As to marketing survey information, there are questions about the trends in the use of drugs, from the standpoint of manufacturer as he schedules production. And then there is the very general subject which must be very high on the list of priorities and that concerns the elements of information with regard to drugs that are necessary for the utilization review relevant to third party payments or government programs. And in the fourth context, there is the question of emergency preparedness. If we had the network, if we had the system operating, could we then achieve proper command and control for the mobilization of manpower and supplies under various circumstances when they will be seriously and suddenly necessary. Now this also touches on many mundane aspects as to the maintenance of the national medical stockpiles so that the drugs in the stockpile are still useful and have not gone out-of-date, and so on. This is a housekeeping procedure which perhaps can be helped by a system procedure of this kind. In the Food and Drug Administration context, there are the problems of drug recall, or warnings relevant to the proper use of drugs. Moreover, from the standpoint of the Office of Emergency Preparedness, there is the problem of disaster preparedness, from which most of us, by the grace of God, are sheltered except unfortunately when the disaster occurs.

I'm sure that there are many bonuses that hopefully you will identify in the Conference which would derive from a system which may be established primarily for the purpose of administration of third party payments. But by looking down the road, can't we somehow do something now which will at least assure that the system is compatible with other data elements and other purposes and other programs, that can be used to accomplish other missions besides the one of immediate concern.

At this time, it is a great privilege and an honor to introduce to you Dr. Cecil G. Sheps, Vice Chancellor of the Health Science Division, University of North Carolina and Director of the Center for Health Services Research. Dr. Sheps.

WELCOME

Dr. Cecil G. Sheps
Vice Chancellor-Health Sciences

My purpose, as you know, is simply to welcome you to Chapel Hill. I'm very glad to have a chance to do this because I'd like to tell you, who are not aware of where a conference like this fits into the overall scheme of the University program, something about our University.

The University of North Carolina at Chapel Hill is the oldest state-supported university in the country. It was started in the last years of the 18th century, some 80 years before the land grant colleges were developed because the government of this state at that early time realized it was necessary to provide higher education opportunities for its citizens. Ever since then this University, while developing and maintaining a very high standard of performance in undergraduate work, graduate work and professional schools, has a very high sense of obligation towards working with the real problems of the community, the state and the nation. One of the reasons for putting together the health-related activities in this University into a Health Affairs Division was to make sure that these different activities in the health fields really related to each other. Alfred North Whitehead, the great philosopher, once said, "When you look at a complicated and vast terrain what you see depends on whose eyes you use." We all know little jokes on that theme. For example, the one about the trumpet player who took a day off and went to a concert given by his orchestra. He realized that when he was going "umpah, umpah", somebody else in the orchestra was doing something else and it really sounded quite different when you were in the audience.

Our Division of Health Affairs here at the University has five professional schools and a number of additional important units of service and research. There are schools of Pharmacy, Dentistry, Nursing, Public Health and Medicine; a large university hospital and a number of special institutes and centers such as the Child Development Institute, the Carolina Population Center, the Health Services Research Center, the Speech and Hearing Center, and the Center for Studies in Alcoholism. All of these are designed to bring together the resources of the University, notably in health sciences, but not exclusively so, in order to solve pressing health problems.

We have about three thousand students in the health affairs section of this campus. Under Dr. Hager's leadership, since he became Dean of the School of Pharmacy, this school, like the other health schools, has greatly increased its enrollment. Thus, we are trying to play our part in meeting the very pressing health manpower requirements of this state and the nation.

Another very notable illustration of the program of the School of Pharmacy in the last few years, particularly, has been its interaction with the other professions in the health field and on the campus. A series of new programs to this end has been developed. They are working very well and illustrate the way in which the pharmacy members of the faculty of this University are marching hand-in-hand with the other members of the faculty. The readiness and the foresight with which this School has grasped the nettle of difficult and new problems - such as drug abuse, and the topic which you will be discussing for the next few days, is also something which we very much like to see. The problems that you are going to be discussing - those of drug information systems - are, of course, of great importance. It happens that I have had some recent rather intimate exposure to the use of computers and other approaches to the problem of identifying and recording adverse drug reactions, in another part of the country, where heavy reliance was placed on a computerized information system. This exposure illustrated to me once again the principle which had been painfully demonstrated to me on a number of occasions before in my professional life. And it is that a machine is a tool, and that if you do not know what you are going to use the tool for and what your objective is, the tool is not of much use. There are some very hard questions that can be decided only by human brain. The tools represented by a computer system clearly can be helpful, but unless these hard questions are answered, the machine system, impressive as it is, is really not very helpful. You have all heard this expressed before - and there is still, regrettably, a lot of justification for it when talking about computer systems -- "garbage in and garbage out." I am sure that you will in the next few days come to grips with questions of this type and will help provide useful and pertinent answers.

The importance of the use of drugs in any health services system is being recognized now more than ever before, not simply because it represents a substantial amount of money, but because it represents greater effectiveness than ever before. It represents a truly important element of health care, a much more effective one than it represented when I was a medical student.

We here on this campus welcome you. While you are meeting here in the School of Pharmacy building and the School of Public Health building, you will be passing a whole series of other buildings on the Health Affairs campus. There also are a lot of other buildings that represent human thought, knowledge, methodology and effort, with which we do our best to connect, particularly in the social sciences. There are all kinds of joint activities that are going on at the departmental levels throughout Health Affairs and through the Institute and Center Mechanism to which I referred, which are designed to bring together all the relevant resources and not to be tyrannized by the organizational structure of schools and departments; but to use these intellectual resources to provide a basis for dealing with the problems. On this campus, for example, we have a department of computer sciences, a department of mathematical statistics, a department of biostatistics and a curriculum in operations research and systems analysis. Just the other day we completed the first phase of arrangements that we hope will produce a research training program in operations research and systems analysis in the health services field. We hope to do this by bringing together all the various resources which we have on the campus.

I am sure not only from what I know about your program this week, but also from my discussions with Dean Hager, that on this campus there has already been made a very interesting and useful beginning in this whole field of information systems and the role that they can play in providing health services to the people of our country to meet the twin objectives of both effectiveness and economy. In his talk this morning Dean Hager outlined a long agenda of possibilities and needs and I am sure that in the course of time, these will, despite the mistakes we are bound to make in the interval, lead us to something which is infinitely better than what we have now.

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DR. HAGER: Thank you, Dr. Sheps. One thing I thought that Dr. Sheps might have mentioned concerns the makeup of our Conference. We had a hundred and eighty advance registrations for the Conference and it does constitute a rather unusual and yet a very important mix with regard to the interests of those who have responded. The Federal agencies are well represented at this Conference by twenty-three registrants, sixteen of them serving as speakers or panelists. This includes the Food and Drug Administration, the Office of the Secretary of the HEW Planning and Evaluation, the National Library of Medicine, the National Science Foundation, and a number of units of United States Public Health Services and Social Security Administration. State agencies are represented by seven registrants. The computer industry and the information services are represented by twenty-six individuals, either as speakers or panelists. There are eight insurance companies and services represented and two of them are speakers or members of the panel. There are two representatives of pharmaceutical manufacturers with us, and three of them are on the program; we have twenty-six participants from the areas of community pharmacy, hospital pharmacy, and the wholesale drug industry. And I am very happy to report that there are sixty-five representatives of colleges, particularly colleges of pharmacy. Nine of them are on the panel.

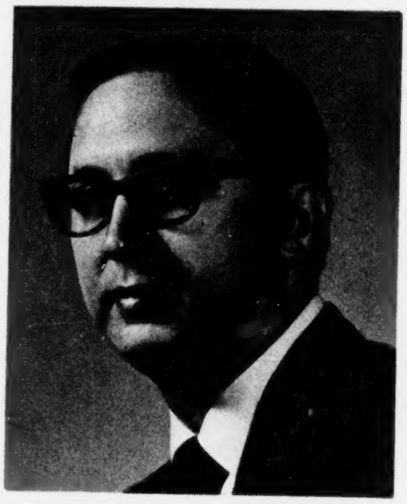
With this kind of a group, and with the right group dynamics, I am sure that we shall have a productive conference. I may tell you that interest in the Conference has also been expressed by a number of persons who are unable to attend. I do hope that we will participate with a broad perspective; that we will not be constrained by what is being done today or by some system with which we are especially involved, or in which we have a strong proprietary interest. We should look at the long range and the broad picture and think in those terms at least in these next two and a half days.

Our first speaker, Dr. Keith Weikel, is Director of Health Evaluation in the Office of Assistant Secretary for Planning and Evaluation of the HEW. Prior to his present appointment in 1970, Dr. Weikel was Director of Health Economics at Hoffman LaRoche, Inc. He has a Ph.D. in Economics, B.S. and M.S. in Pharmacy. It is a privilege and a personal pleasure to introduce to you, Dr. Weikel.

1. INFORMATION SYSTEMS IN THE PHARMACIST'S MODERN ROLE

MEDICAL DATA AND NATIONAL HEALTH PROGRAMS

M. Keith Weikel, Ph.D.
Director, Division of Health Evaluation
Office of the Secretary, HEW



In discussing the year 2000, Dr. Daniel Bell, one of the nation's leading futurists wrote: "The future is not an overarching leap into the distance; it begins in the present." With this in mind, it may be instructive to look at some of the problems confronting medical care and medical data systems in the past and the present before we discuss the impact medical data systems will have on health care in the future.

In October of 1932, the Committee on the Costs of Medical Care indicted the existing health care system with the following statement:

> "The problem of providing satisfactory medical service to all the people of the United States at costs which they can meet is a pressing one. At the present time, many persons do not receive service which is adequate either in quantity or quality, and the costs of service are inequitably distributed. The result is a tremendous amount of preventable physical pain and mental anguish, needless deaths, economic inefficiency and social waste. Furthermore, these conditions are largely unnecessary. The United States has the economic resources, the organizing ability and the technical experience to solve this problem."

In the intervening years, most of the problems outlined by the committee remain unsolved. Few dramatic changes have taken place in the past forty years. President Nixon indicated in a recent statement that there still exists the danger of "a massive crisis in health care." Others have expressed the concern that the crisis is already upon us and that drastic changes are needed immediately.

But the problem is not simply one of devising health care programs for the future. There is an equally pressing need to undertake a searching examination of programs implemented in the past. I am sure that you are all familiar with the "Report on the Health of the Nation's Health System." The report made several recommendations. The one that is of most concern to Federal officials is the following:

> ". . . that we demand of ourselves and the Federal Government in general, that we put our own house in order, including reviewing the role and performance of Federal health programs."

Unquestionably, there is a serious need to review the effectiveness of existing Federal Health programs. Federal evaluation is and will continue to be undertaken with respect to the effectiveness, efficiency, quality and accessibility of those various programs. To facilitate this evaluation, however, as well as to design programs for the future, rapid, reliable, and accurate data systems are a vital necessity. This is especially true in light of the growing complexity of the problems confronting the health care system.

Good, comprehensive data systems are needed in all sectors of the health care system, if the quality of services is to be improved and programs operated more efficiently. In the area of pharmaceutical services, for example, there is a need for good patient histories, with information on drug utilization, previous drug reactions, and a complete medical chronology on illness, allergies and any other physical dysfunctions. There is a need for comprehensive data to enable both private and governmental sectors to make better decisions about the allocation of scarce resources. There is a need for a modular data system that will enable both private and government interests to access and obtain required information. That system must, however, account for the pluralist nature of the American socio-economic mileau. Needed is a modular system which will allow for maximum adaptability and interchangeability to meet the various and wide ranging needs of its users, public as well as private. In addition, there is a need for comparable data systems on state, local and regional levels to meet their specific needs.

Drug Utilization Review

With this admittedly cursory introduction, let me now move into a somewhat more detailed examination of one possible data system -- in the area of pharmaceutical services. I would like briefly to discuss one of the more vital functions which such a system would facilitate -- drug utilization review.

It is likely that third party payments will soon cover a large part of all prescriptions dispensed in the United States. A sophisticated EDP system will be necessary to collect and process prescription drug records. The ideal system would make it possible to record all prescription drug sales in the United States by using devices capable of transmitting such information directly to computers through source data automation. The system would be capable of accommodating a number of users, such as private and government drug insurance programs, billing for credit prescription sales made by retail pharmacists, facilitating inventory control, and reordering for prescription products.

One of the primary functions which might be carried out through the establishment of such a system is that of utilization review. Simply stated, drug utilization review is the computer-based monitoring of the prescribing, dispensing, use, and cost of drugs in order to minimize improper utilization and to improve the quality of patient care. It incorporates peer-established standards for prescribing, cost containment, evaluation, and remedial action.

Comprehensive drug utilization review, to be most successful, must rely on a highly sophisticated data system. It depends on a computer-compiled data base incorporating the prescribing practices of physicians, the dispensing patterns of pharmacists, and the consumption habits of patients. Such a base can be developed in third party payment programs during the course of claims processing. As vendor claims are processed for payment, data can be captured with respect to: the identification of the physician, vendor and user; the drug prescribed; directions for use; and charges to the program. From the assembled data, profiles can be developed which allow a utilization review committee to isolate prescribing, vending and consuming practices which deviate from pre-established standards. Peculiarly administrative deviations such as fraud and abuse can be easily rectified through the payment process itself. Major problem areas (for example, inappropriate prescribing by physicians) must be tackled within the context of professional education and guidance.

There are in the United States today two operational utilization review systems which incorporate, to one extent or another, many of the system design features necessary to a successful review program.

The prime objective of both systems is to aid in the achievement of high standards of patient care through the promotion of rational drug therapy. (Rational drug therapy was considered by the HEW task force on drugs to mean prescribing the right drug for the right patient at the right time, in the right amount with due consideration for relative costs.)

The San Joaquin Foundation for Medical Care has developed a retrospective utilization review program. The system, through the claims processing function, is designed to identify patients receiving high dollar amounts of drug, patients receiving high numbers of prescriptions, inadequate quantities, duplicate claims for drugs, invalid claims, and other factors which may influence either utilization or the cost of the drug program. When discrepancies occur, cases are submitted to either a pharmacy or a medical peer review committee.

The program of the Los Angeles County Medical Center is an on-line system designed to provide the physician and the pharmacist with complete up-to-date drug histories for patients prior to the dispensing of medications. Only after such a review is the medication dispensed. The data are then entered immediately into the system. Through the data so captured, prescribing patterns for physicians are reviewed by a committee using established parameters to define inappropriate quantities, inappropriate quantities theoretically in the patients' possession, inappropriate concurrent prescribing, inappropriate drug use and inappropriate dosage for intended use. Despite incomplete parameters, which must be further refined, the program is already unearthing certain prescribing practices which account for a tremendous concentration of inappropriate prescriptions. Thirty out of 820 physicians, for example, accounted for fifty percent of all inappropriate prescribing.

Implications of Drug Data Systems

Perhaps the least discussed and potentially most valuable asset of sophisticated drug data systems is the wealth of data which will be made readily accessible through their continued use and refinement. Careful scrutiny of the data so generated will shed considerable light on a number of relevant subjects.

Readily accessible information on drug use will also facilitate epidemiological studies, thus enhancing the extent of knowledge about the use and effect of various drugs.

Cost-benefit analyses on the ratios of increased health services to monies spent are another vital part of any future health care scheme. While in theory the procedure of cost-benefit analysis is fairly clear-cut, in practice it is often difficult to operationalize the variables in a given situation. For cost-benefit analysis to be effective, it is important to have data available in sophisticated, detailed, and flexible form. Well-developed drug data systems will provide such data.

Finally, I cannot stress emphatically enough the importance of utilization review. Unless some mechanism for review and control is built into any health scheme, planning, organization, cost and utilization control are useless theoretical concepts. For instance, one hundred percent comprehensive peer review of each and every incidence of service is not only impractical but impossible from the standpoint of time, personnel, and monetary expenditures. Once, however, effective treatment, diagnosis, and prescribing parameters are defined and quantified, a sophisticated drug data system will facilitate peer review. In fact, perhaps the most potentially useful data to be collected by medical data systems will be in the area of utilization review.

All of the data which will be made available -- be it for socioeconomic and demographic studies, for cost-benefit analyses, or for utilization and peer review -- will be useless unless they are understood and used by the persons who should find them valuable. It might be worthwhile at this juncture to examine the potential impact data processing systems may have upon both the consumers and providers of health care services.

The immediate beneficiaries are the patients. The increased information available to the physician for diagnosis, treatment, and prescribing will enhance the quality of medical care. Because physician activities will be subject to review, there will be increased impetus to establish the most rational parameters of drug treatment. Physicians will be induced to adhere to these parameters.

Drug data systems will tend to reduce the number of adverse drug reactions. Pharmacists, and in many cases physicians, will review previous medications prior to a new prescription. Furthermore, computers may be equipped to spot automatically dangerous contra-indications.

The impact of drug data systems on physicians is more controversial. Assuming that physicians make use of new data systems available to them, increased patient and drug data should be helpful in choosing those drugs most appropriate in light of a patient's medical history. Here one can anticipate the following developments:

(1) Effective utilization review will result in the improved coordination of drug prescribing by diagnosis.

(2) Once established, maintenance of suggested treatment, prescribing and diagnosing parameters will lessen the possibility of over- or under-utilization of drug and related services.

(3) The threat posed to a physician by the close monitoring of his prescribing practices will be alleviated once the physicians realize the benefits of drug data systems and learn to accept as constructive criticism the potential errors which the data system may reveal.

Pharmacists will be affected by drug data systems in several ways. Considering the present growth in drug utilization, the possible diminished use of hospitalization, and the removal of money barriers to the acquisition of drugs, estimates suggest that within five years, the number of prescriptions dispensed in the United States may double. Efficient drug data systems will assist in the dispensing of drugs so that the pharmacist will not be swamped by the resultant paperwork.

There will be increased utilization of the pharmacists' professional knowledge and training. The pharmacist will have knowledge of the diagnosis and be expected to link new prescriptions with the patient's previous drug history; he may thereby be required to assist in the physician's decision as to which drug to dispense.

Thus, the concept of the clinical pharmacist again comes alive. Most schools of pharmacy have incorporated into their curriculum some variation of the clinical pharmacy concept. One possible application of such training could be in predispensing decision-making which will accompany many drug data systems. Finally, a party to the nation's health care system which obviously will be affected by the drug data systems which we have discussed today is the pharmaceutical manufacturing industry. Many issues which the industry has already confronted will gain more prominence. Perhaps some of these will move more readily toward resolution with the advent of sophisticated data systems. For example,

(1) The volume and accuracy of marketing of clinical data on drugs

(2) There will be increased pressures on manufacturers to justify why their products should be included under third party payment programs -- especially if they account for a significant percentage of any program's drug budget.

(3) The industry will experience downward price pressures as a result of moving from a situation of many small purchasers to one of a significant increase in purchasing power as third party payers pay for larger and larger percentages of the drug bill or industry output.

(4) The brand versus generic question may be discussed in more rational terms by both government and industry if more sophisticated data systems shed additional light on the economics and clinical aspects of drugs. We would suggest, however, that this is a false issue for the following reasons:

(a) We know of no responsible individuals in the executive branch of our government who advocate the prescribing of inferior products in government programs. However, many of these programs are constrained by budget and thus, must be concerned with price as well as quality.

(b) If the price differential between multi-source drugs were less, there would be few government officials recommending purchase of so-called generic drugs.

(c) The key question in regard to this issue is the reliability of the manufacturer and not whether a product is sold under a brand or generic name.

(5) Finally, the industry will find it critically important in the future to conduct socio-economic studies for all their drug products in order to approximate what contribution they are making to medical care. It will be important to know the cost to benefit ratios for all products. Socio-economic studies should be conducted at the same time as clinical studies.

In short, for the manufacturer we see a drastically changed environment which will require re-examinations of most past marketing practices.

I have attempted to discuss some of the economic, social, and practical applications of drug data systems to the health care systems.

Let us not forget, however, that all of the machines in the world are of little use unless there are well-trained health professionals to review and utilize the available statistics. It is, therefore, important for us as health professionals to prepare to meet the challenge of the computer age and to apply its benefits to an enhanced health care for the American public.

*THE PATIENT, THE PHARMACIST, AND DRUG INFORMATION NETWORKS

Vernon F. Wilson, M.D., Administrator
Health Services and Mental Health Administration, HEW.

It is a special pleasure for me to be addressing this Conference. You are meeting to discuss a subject that is of paramount interest to me, personally. Much more importantly, it is a subject that will occupy a rapidly growing share of national attention in the years immediately ahead. How well we handle the problem of data-gathering and data-sharing will determine in large measure our success or failure in handling the challenge of health care.

The health care system is unique, in many ways, among our American institutions. It represents an enormous investment -- some 60 to 70 billion dollars are spent each year by the American society in pursuit of health. The health care enterprise is one of the Nation's largest employers. It touches the lives of every man, woman, and child; and its product stands at or near the top of everyone's priority list of needs and desires.

And yet, we have no accepted and measurable definition of the product. We have no creditable information on the distribution of good health. We do have some rather crude indices of what happens when it is absent. Moreover, our capacity to measure the performance of providers of health services in either quantitative or qualitative terms is rudimentary.

On the economic side, we have only a few approximations of what the consumer buys with his health care dollar as compared with what he ought to be able to buy. How can all this be true of an enterprise so vast that it consumes seven percent of our Gross National Product?

In part, no doubt, the answer stems from the peculiarly personal nature of the health care process. A man's health or illness is his own affair, and the transactions involved are jealously and scrupulously guarded. At the same time, our western cultures have nurtured

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*Read by Donald C. Brodie, Ph.D., Director, Drug Related Studies, National Center for Health Services Research and Development an abiding thread of suspicion of the machine from Mary Shelley's Dr. Frankenstein to George Orwell's 1984. We have wondered what the Monster or Big Brother would do to our human values. Perhaps some combination of these factors has prevented the health care system from moving into twentieth century technology -- particularly, in the management of information. Conferences like this one, however, and the work being done by many of its participants indicate that we have begun to move.

The Health Services and Mental Health Administration, which, as you know, is the agency within HEW primarily concerned with the organization and delivery of health care, has been engaged over a considerable period of time in identifying our most appropriate roles within the system. We have proceeded from the basic assumption that what we do, as a Federal agency in the national health partnership, should complement that which is done by the private sector. We should identify and stress those functions that, for various reasons, are not performed adequately outside the governmental sphere.

Each time we consider this proposition we reach the conclusion that the field of information handling is particularly appropriate for our participation. Within our agency, we have unique resources for leadership in this field. The National Center for Health Statistics has been for many years the leading Federal instrument for collecting and disseminating vital statistics as traditionally defined. The National Center for Health Services Research and Development, more recently established, has as its principal charge the fostering of more efficient and effective patterns of health care delivery through the application of scientific methodology.

A number of other programs within HSMHA represent both generators and consumers of health data. The Community Health Service supports comprehensive health planning efforts in States and areas across the country, and planning without data is plainly an exercise in futility. Regional Medical Programs are designed to forge effective linkages among provider systems; and these, again, must deal in creditable information. The Maternal and Child Health Service, National Center for Family Planning Services, the National Institute of Mental Health -- in fact, all of our programs -- depend on data for assignment of priority and assessment of progress.

A quick look at the broad range of challenges before the health care delivery system indicates very clearly that improved data management is among our highest priority needs. Rational decision-making for any important investment requires reliable and continuing data. When the decision-making process envisions major changes on a large scale, as is now true in the health field, the urgency is further heightened. In recent years, the health care system has undergone tremendous expansion without an accompanying refinement of its baseline data-gathering and handling mechanisms.

There is another dimension to this need. Health care decisions should be made as close to the people as possible. The accent is on decentralization to the States and communities, each of which has its own unique constellation of needs and resources. Therefore, to be responsive, a data system must be based upon and relevant to a multiplicity of local situations. This is not a new idea; to illustrate, England has initiated efforts to provide permanent health records for her citizens. We should be striving toward this same goal, but we should also profit from some of the difficulties inherent in such an enterprise.

Therefore, HSMHA is embarking upon a program to support the development of a cooperative Federal-State-local health statistics system. Its initiation is based on legislation enacted last year that provides the Secretary of HEW authority to "undertake research, development, demonstration and evaluation, relating to the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State and local levels."

Accordingly, we are asking for funds in the Fiscal Year 1972 budget of the National Center for Health Services Research and Development to enable us to get underway. We are proposing developmental projects in selected communities, States, and regions; these efforts are designed to create modules of a cooperative data system that can be replicated and implemented throughout the Nation in a later phase.

We are only beginning to comprehend the interactions among drugs, between drugs and diet, and between drugs and age. Adverse reactions to drugs are still irregularly reported. Patients often use drugs prescribed by two or three health professionals; the patient usually does not realize the potential for incompatability, but the pharmacist can be the catalyst or communicator in these cases.

As you may have noted, I have taken some liberties with the title of these remarks as indicated in your programs. But, in Dean Hager's first letter to me, in late March, he indicated that this Conference and the subsequent workshops would revolve around the theme of "The Patient, the Pharmacist, and Drug Information Networks." That simple and direct thrust impressed me, because that, really, describes our mutual concerns and objectives. Furthermore, the most important part of the package -- the patient -- is properly placed; that is, first.

One of the most critical problems in organizing the delivery of health services is the point of entry for the patient into the health care system. Gone are the days, at least for the time being, when everybody knew who "the doctor" was and lived near one. Two significant developments of the past few years -- the neighborhood health care center and the reawakening of interest in family practice as a medical specialty -- represent attempts to deal with this problem.

Although such approaches are valuable and necessary, they answer only part of the problem. Far too often, if we wait for the patient to get to a doctor, it will be too late to help him -- especially if he suffers from one of the chronic diseases, which increasingly dominate the Nation's health problems.

Pharmacy has a unique characteristic for helping to accelerate entry into the system. That characteristic is reasonably equitable geographic distribution. As a physician, a medical educator, and now a Federal health administrator, I have always seen the pharmacist as an indispensable, full-fledged, member of the health team.

But what appears to be self-evident to me seems to be obscure to many others. It is painful to note that the positive role of the community pharmacist is frequently misunderstood, undervalued, and sometimes overlooked.

Despite a rigorous education, despite professional experience and expertise, and despite high visibility of the pahrmacy in every shopping center, the pharmacist could become the forgotten man -- a valuable but unused resource in health service delivery.

The fact is that while here and there health centers are being located in urban neighborhoods and doctors have opened offices in suburban shopping plazas, pharmacists are already on the scene with accessible, walk-in facilities. Their presence is made visible in large letters and neon lights. Pharmacists, in short, are ideally positioned to serve as a first point of planned contact between the patient and the health care enterprise.

But, if this unique position is to be developed and exploited for the benefit of patient and the health care system alike, it will be necessary to examine and to consider changing the nature of that initial contact. Today, the role played by the pharmacist in his contact with the patient tends to be one of two kinds -- either of the highly limited professional or of the merchant. As a professional, he is carrying out a highly skilled but very narrow task ordered by a higher authority. As a merchant, he is responsive to the general dictum that the customer is always -- or almost always -- right.

At this time, many proposals are being advanced and developed for what might be called "instant physician assistants." Individuals with limited educational preparation are being considered for important health care roles. At such a moment, pharmacy should carefully consider its future.

What is needed here is the utilization of the pharmacist as a broad-gauged health professional, serving the patient as a special kind of initial health consultant. His responsibilities could range from the operation of a simple screening service and primary health counseling to referral to an appropriate source of advanced service. After advanced diagnosis and prescription, his function should include counseling to make sure that the patient fully understands and intends to comply with the prescribed drug regimen, and follow-up to be sure that he does so.

Although many hospitals have adopted single-patient unit packaging equipment directed by pharmacists to conserve the energies of nurses for more direct patient care, few facilities have utilized all of the by-product data from this operation. The computer that facilitates faster processing of medication orders can also enhance opportunities for quality control procedures. The computer that feeds billing and drug inventory information to the business office can also establish patient medication profiles to guide future medical care.

Several other by-products of the health-facility-based computer could be easily programmed. The computer could reject orders for drugs that are outside the accepted dosage range, that would be administered by an inappropriate route, that would be combinations of incompatible chemicals, and, that should have been preceded by reports of specific laboratory tests. The computer could also be programmed to indicate that the drugs have already been ordered, that a newly prescribed product is likely to react with a previously prescribed drug or diet, or that the patient is allergic to an ingredient in the drug. Furthermore, the computer could remind the nurse to record both the administration and monitoring observations of a drug regimen; the prescriber could be reminded to order appropriate laboratory tests due after a specific amount of medication has been administered.

The pharmacist who yearns for greater challenge can certainly find it in this new field, because even more exciting possibilities will develop only when large numbers of patient records are computerized and when all are using standardized nomenclature.

Furthermore, the doctor will then be providing and the patient will be receiving better care.

Moving into an area more closely related to the pharmacists' traditional function, it seems to me that the changing order of priority of illness in this country must imply changes in pharmaceutical practice. With the increasing prevalence of chronic diseases and mental illness, we have a rapidly increasing proportion of patients on drug maintenance programs, often involving a variety of drugs over protracted periods of time. Instead of the one-shot medication typical of a bygone era, drug regimens are sustained and complicated.

In these circumstances, can the physician be asked to shoulder the entire responsibility for the safety and effectiveness of drug therapy? Should he be the one with exclusive concern for synergistic effects? The pharmacist has readily available information to determine whether or not a patient on a certain combination of drugs can safely drive a car. What should be the respective roles of physician and pharmacist in follow-up to assure that the patient is complying with medication orders? What kinds of record-keeping and feedback of information should we be developing to monitor modern chemotherapy?

I recognize that I have totally neglected, thus far in my remarks, the genuine and rapid evolution of the pharmacist as a professional member of a health team in the institutional setting. Progress in hospital pharmacy has been among the highly important advances of the past few years. Most importantly, the teaching hospital has prepared "patient-oriented," rather than "drug-oriented" pharmacists.

The rapid growth and continuing extension of prepaid, comprehensive health care plans carry important implications for pharmacy as well. There is an obvious need for pharmacists to participate in these plans in a contractual relationship between providers and users of health care.

Obviously, this is not to say that drug management in hospitals cannot stand further refinement and improvement. But, I feel confident that the momentum behind this trend will assure that improvements will come. I am more concerned about assuring comparable progress outside the institutional walls, in the community at large.

As we move toward activating the patient as a protagonist rather than a passive receptor in the health process, I can envision the neighborhood pharmacy as a patient education center with kits of material or programmed educational tools. The pharmacist should become a civic health educator and could participate in meetings of service clubs, parent-teacher groups, youth organizations, and neighborhood self-improvement projects.

Furthermore, based again on the location of pharmacists near people and their special interrelationships, I wonder what the profession might do to respond to, or even prevent, a community health emergency. What might have been done by the pharmacists of San Antonio, for example, if they had acted in concert in response to the knowledge that 75 percent of the city's school children were not immunized against diphtheria? By urging immunization through the person-to-person channels at their command, might they have blunted or even prevented last summer's outbreak?

Modern medicine is being affected simultaneously by both centripetal and centrifugal forces. The great centripetal force is generated by advancing biomedical science and technology that pull the system inward toward the great medical center where equipment and expertise can be assembled for the performance of wonders. The centrifugal force is produced by public need and public demand for care that is accessible and relevant to family and community life.

The health professions -- and here I include medicine, pharmacy, and all the rest -- need to be aware of and responsive to both kinds of forces. Otherwise, we will fail to deliver the full measure of our potential, and we will fail to satisfy the full measure of public expectation. Whether or not we meet this impressive challenge in the years ahead depends, to a very considerable extent, on how we prepare oncoming generations of health professionals. It will also depend on our ability to overcome sensitivities that obstruct achievement.

Robert Ardrey, in Territorial Imperative and African Genesis, eloquently demonstrates that winning and protecting a given territory is among the fundamental drives of animals from the warbler to the warthog, including man's next-of-kin among the primates. He suggests that this animal heritage may explain a good deal of human behavior as well.

I am inclined to agree with him, having observed the phenomenon in university faculty meetings and more recently in the councils of government. It takes a relatively short leap of the imagination to see the territorial imperative at work in the formation or nonformation of functional health teams. Each profession is all for teamwork as long as it does not involve surrender of a hard-won "turf."

But in the health field there remains a great expanse of territory, in terms of work to be done, that is as yet unclaimed and undefended. It seems to me that the secret of really successful collaboration among the health disciplines may lie in exploring these undeveloped areas and in identifying those professions peculiarly qualified to develop them. The territorial imperative as it applies to professional education and practice constitutes a formidable obstacle. However, I think we can handle it; but, to do so, we shall need to support wisdom over protective instinct, which is not the usual human modus operandi.

To be accepted fully by other health professionals, the community pharmacist must begin by accepting his own image as professional. If I may venture to say so, his role in the health care system has until now, been too passive. What is required by our Nation's health needs is active participation by pharmacists in the delivery of health care.

I recognize that some of the functions I am suggesting are, in fact, being performed by some pharmacists, some of the time. But I feel that we should ask whether as a national policy the role is emerging fast enough -- particularly in drug utilization review and control.

The misutilization of prescribed drugs, which results in a national waste at the multi-billion dollar level, must be recognized as a major public health problem. In existing programs of utilization review, the work of professionals is usually reviewed by other professionals in the same field. Neither physicians nor pharmacists are prepared for a review process that extends to drug utilization and that involves the pharmacist in a review and control function of prescription activities or the reverse in pharmacy practices. From both sides, there is need to stimulate interdisciplinary contacts and understanding, so that the health care system can deal with the totality of the basic problems of drug utilization control.

Pharmacy organizations need to develop the concept of responsibility in drug utilization review as a component part of medical review. Due to past experience, individual pharmacists will often not participate without the support and, perhaps, the prodding of pharmacy organizations, which ought to seek out the members who are most competent to serve. A primary objective should be to make drug utilization control an integrated component of the health care delivery system.

Every neighborhood pharmacist can contribute to the control function by routinely checking prescriptions, by calling the physician as necessary, and by broadening his knowledge of the biological effects of drugs and drug-related patent problems. Pharmacists who maintain patient drug profile histories should be recognized and commended.

To become fully worthy of its professional ideals, I believe that pharmacy will need to accept and strive for the idea of evaluation of its own work. Wouldn't it be a great advance if pharmacy as a profession worked to set up quality standards to meet today's health care needs? There would be no more convincing demonstration of the fact that, so far as pharmacy is concerned, the patient comes first.

And to the extent that the patient's well-being becomes the social reason for the existence of the neighborhood pharmacy and the ultimate measure of its performance, the pharmacist will protect and enhance both his professional and his commercial status.

I fully recognize that not all of the elements I have mentioned can be implemented in practice by all community pharmacists. But I suggest that nearly all community pharmacists can and should broaden their role in the health care system. There is considerable urgency for doing so.

The health care system in this country is in ferment as never before. Although many Americans receive care equal to the best found anywhere in the world, millions of others -- particularly the urban and rural poor -- are provided care on a haphazard, emergency basis. Comprehensive care of good quality is, in fact, hard to come by, although most of the population now regards it as a fundamental right.

As the things that people expect from the health care system broaden and crystallize, their expectations increase the pressure on both health care providers and health care administrators to institute changes in the health care delivery system. At no time in our history, has the pace of change and transformation been so rapid.

What about the supply of pharmacists? Do we have enough trained manpower? Unlike physicians and nurses, pharmacists are not conspicuously in short supply, at least for the time being. Although less serious than in other health professions, the current problem is maldistribution. It would seem feasible to me that local organizations of pharmacists could assume responsibility for the provision of pharmaceutical services in small communities and small hospitals where they are not available. Where only one pharmacy serves a large area, it might begin experimenting with outreach stations. Here, again, it could well be the professional organization that initiates the survey and determines the need.

All of the health professions in the United States today are challenged by their own excellence. What we have done for some of the people we serve is the measure of expectation of all who seek service. To meet that expectation, every profession needs to stretch itself and to find new ways of exploiting its unique contribution to health.

More than that, each profession needs to submerge its territorial drive in a common quest. And together we need to reach out to include the patient, not as the object but as the active subject of health care.

I have expressed the creed that the patient comes first. The health practitioner who lives by it will not only serve the community well, but will survive and prosper.

Colloquium

T. Donald Rucker, Ph.D.

Chairman

PHARMACY AND THE COMPUTER

Ralph Engel
Director, National Pharmacy Insurance Council

The profession of pharmacy is witnessing evolutionary changes which will undoubtedly affect its traditional practice.

Third-party drug programs have created a mountain of paperwork. If we are to avoid changing the pharmacist from a health professional to a bookkeeper, we must consider affecting a uniform, streamlined procedure utilizing a national drug information network to cope with this new challenge.

Background

Prior to the early part of the 1960's, pharmacy involvement in third-party programs was restricted to either vendor payment programs under state public assistance laws or to completing information on forms provided by private insurance carriers to insured persons covered under major medical insurance which happened to include prescribed drugs. Until recently, drug insurance has been hampered because of various economic, administrative, legal and theoretical constraints. But despite this, drug insurance for out-patients today seems to be a growing force on the health care scene.

Virtually all wage negotiations contain health care demands, and the majority contain demands for out-patient prescription drug coverage. In 1970, nearly ten percent (10%) of the approximately 1.5 billion prescriptions dispensed in the United States were covered by a prepaid health care program. We estimate that by 1975, some fifty to sixty percent (50-60%) of a projected 2.5 billion prescriptions dispensed will be covered by the combined enrollments under private and public insurance plans. Moreover, when and if National Health Insurance is enacted, this figure could jump to as much as ninety-five percent (95%) -- a fantastic growth in the number of prescriptions, but an even more fantastic growth in third-party payment. On top of all this, no large increase in the number of pharmacies is foreseen. Thus each pharmacy will be called upon to dispense more prescriptions.

When pharmacists were dispensing by what is today's standards a relatively small number of prescriptions, an insignificant proportion were paid by either public assistance programs or commercial insurance companies. The necessity of finding a faster means of obtaining and transmitting desired information was not considered a problem. The proliferation, not only in the number of prescriptions being dispensed, but also in the number of prepayment or insurance programs designed to cover the cost of prescribed medication, has now necessitated a closer examination of the problems.

Problems

Most pharmacists are concerned over the increased amount of clerical and record-keeping procedures required under prepayment programs as well as those necessary to provide good professional care. They fully recognize that the maintenance of good patient records is critical to an integral and desirable professional pharmaceutical service but that it is becoming an increased burden both financially and physically.

A number of programs place the responsibility for determining the patient's eligibility to receive medication upon the pharmacist. Some think they are aiding the pharmacist in making his decision regarding eligibility by providing a multiplicity of color coded cards, each signifying various types of coverage, or a "hot list" noting the ineligibles. In reality, they are making increased demands on the pharmacist's time.

Private insurance carriers are, in many cases, providing the insured with a plastic identification card indicating the insured's name, a unique identification number, the expiration date of the insurance contract, and quite frequently, the type of plan as well as the number of dependents covered. Here, too, valuable time is lost as the pharmacist must interpret the various cards. Further, the private plans utilizing the plastic identification card necessitate the pharmacy's investment in either the purchase or rental of a number of hand-operated imprinters, which are not interchangeable. While this procedure eliminates a portion of the necessary handwriting, it is not able to reduce the ever-increasing work load of hand preparing numerous insurance claim forms by the pharmacist.

Each of the carriers utilizes its own claim form, creating a horrendous problem in itself. There are pharmacies in this country which literally have anywhere from sixteen to twenty different forms and the pharmacist spends more time sorting and preparing forms than he does in actual practice. Several carriers are utilizing the services of third-party administrative agencies formed for the specific purpose of processing prescription benefit claims. These companies have their own systems; there we have the superimposition of one system upon another.

Progress to Date

In an effort to relieve some of the current problems facing the pharmacist today, NPIC, through its Administrative Processes Committee, has outlined procedures necessary to expedite identification of eligible recipients of drugs as well as those steps necessary to alleviate the problems of processing the multiplicity of claim forms. It recommends that program subscribers identify themselves by a plastic card supplied to them by the insurance carrier or third-party administrator. The information required on the plastic identification card should have a uniform format.

Pharmacy has designed a claim form which has universal application today. It is constructed to adapt to any method of administration, from hand-sorting to sophisticated electronic data processing, including optical scanning. It was developed for both the service benefit program as well as the indemnity type of program.

The Administrative Processes Committee also recommended that a pharmacy identification code be developed and noted that it should be adaptable to all areas of identification pertaining to pharmacy and should be available to complement the Pharmacy Claim Form. At this time, the code does, in fact, exist and most pharmacies have been so notified.

The significance of both the "Pharmacy Identification Code" and "Pharmacy Claim Form" is far-reaching. When utilized by all third-party carriers and administrators, it will help reduce the cost of administration and equipment and speed up payment to the pharmacist. Also claim identification and adjustment will be greatly simplified.

It was conceded at the beginning of our efforts that a paper system was not the ultimate answer to our problem but rather a step toward the more sophisticated EDP systems. When we first began this project, the Administrative Processes Committee compiled nearly forty (40) distinct items appearing on a multitude of forms. Since that time, several obvious changes have occurred which have enabled us to reach the point where we feel that the Pharmacy Claim Form contains all data elements necessary for any drug program. The problem is to transpose these elements to a suitable computer terminal operation.

The application of EDP to the processing of patient pharmaceutical data is of prime concern to the entire pharmacy profession and its individual practitioners. Such a system could produce meaningful reductions in the repetitive and excessive forms-handlings, and prescription labeling procedures associated with the traditional preparation and processing of prescription orders, and the resulting record-keeping responsibilities.

Since the daily demands and duties associated with pharmacy practice occupy important time and resources, it is logical that the pharmacist would welcome a means to relieve himself of these pressures and to assist in determining methods of record-keeping to expand his knowledge of the patients he serves as well as his pharmacy practice. A direct result will be a more patient-oriented practitioner.

Advantages

As I mentioned earlier, prescription volume is constantly growing with an estimated 2.5 billion prescriptions to be dispensed by 1975. Electronic terminals installed in pharmacies for direct transmission of data to high speed computers hold promise of providing an economical and feasible mechanism for processing the great volume of claims which are expected. As a matter of fact, it has been stated that any sizeable drug program would be severely retarded without such equipment.

At this point, let's examine some of the advantages of an EDP system as it pertains to the practice of pharmacy. They are not necessarily in the order of importance, but are the ones most frequently referred to and discussed.

1. Reimbursement delays could be significantly reduced. The speed of transmission for each claim would be reduced considerably and can be processed by computer, thus avoiding the delay of manual manipulation.

2. Myriads of paperwork will be eliminated. The need for claim forms can be avoided in most cases. We do recognize, however, that some pharmacies will require paper as a back-up system.

3. The cost of processing third-party claims should be reduced. Contemporary claim processing costs under currently operating drug programs range anywhere from approximately twenty cents (20¢) to around two dollars and fifty cents ($2.50) per claim. The average cost is over one dollar. The use of an EDP system could possibly reduce this cost by nearly seventy-five percent (75%).

4. Patient profile records are maintained. Good patient care demands good record keeping, and only with computer technology can the pharmacist hope to capture, correlate and store information to make it available for proper retrieval and review.

5. Drug interaction and compatibility can be monitored. This information can be stored in the computer and retrieved quickly for review. It is important to recognize that the patient profile records should contain non-legend drugs being used as well as prescription items. This is particularly important from the standpoint of drug interaction and drug compatibility.

6. Patient eligibility can be instanteously established. Several programs require that eligibility be established before the fact. With on-line equipment, the burden of establishing the same is placed back where it belongs and not on the pharmacist.

7. Inventory control may be maintained by the computer. Inventory data could be transmitted to the supplier of choice (wholesaler or manufacturer) to automatically reorder stock within given parameters. With this system, the method of replenishing stock at the pharmacy level would be optimized.

8. Accounts receivable. The pharmacist may, through the same equipment, operate his charge system, and have his billing done through the computer. Many are doing this today.

Information Required

What information would be sought in order to obtain the advantages of an electronic data system? The following data elements are certainly relevant and "quite by coincidence" come from the Pharmacy Claim Form.

1. Pharmacy identification,
2. Patient identification,
3. Dependent identification,
4. Pharmaceutical product or health-related item prescribed,
5. Insurance carrier identification,
6. Prescription number,
7. Refill data,
8. Physician identification,

9. Amount of charge,
10. Quantity dispensed,
11. Number of days of medication supplied, and
12. Date of dispensing.

Once these elements are massaged and made a part of the entire picture, other benefits can be obtained from the use of automation. Such things as utilization review can be carried out using the data just enumerated. This professional function holds great promise for both improving the quality of patient care as well as controlling its cost. Control of drug abuse can be initiated by the examination of patient, dispenser and prescriber records. Also the diversion of dangerous drugs can be monitored to a degree.

Concerns

We have reviewed some of the positive points with respect to the automation of the pharmacy, but there are some concerns, or disadvantages, if you prefer. The first consideration in automating the pharmacy is the pharmacist himself.

The introduction of EDP equipment must not require unreasonable procedure changes nor increase his work load, when, in fact, the purpose is to make the job easier. We don't want the cure to be worse than the disease.

Another great concern is who is going to pay for this new equipment. Pharmacists are not going to bear the cost, nor should they have to. To get widespread acceptance, there will have to be a cost sharing procedure. If a wholesaler or manufacturer obtains drug inventory data on an aggregated basis, they could not only supply the products needed, but could establish their own levels of inventory. The manufacturers could also obtain sales data on a given product, all of which indicates that they should share in the cost. If government obtains statistical information, it should indeed pay its share. In the case of private carriers, if information is sought for actuarial purposes, then a share of the cost must be borne by them, and so forth.

Who is going to maintain the equipment, once it is installed? All of us are aware that a machine, however sophisticated, has its down time. Will it require special techniques to operate the terminal device, thus requiring special personnel? Also, space requirements are of concern. The equipment cannot be so large as to be out of proportion with the pharmacy department. We cannot ask the pharmacist to redesign his environment to meet the requirements of a device.

Versatility in programming is important. Also, there is a concern or fear on the part of the pharmacist that his confidential relationship with the patient may be lost. Along these lines, there is also the feeling that such a device in the pharmacy could well be an invasion of privacy, since over the course of time, all of his business data will be disclosed. Swinging the pendulum the other way, several pharmacists have even voiced the question: will an adequate device be ready in time to alleviate the anticipated burden?

And last, but certainly not least, is what is referred to of late as the "Black Box Syndrome." This syndrome is characterized by hot flashes, sweating palms, loud grunts, and doubting looks. Seriously what I am trying to indicate is the fact that many pharmacists, as well as the general public, tend to lack confidence in computers. Their concern is that once they would transmit a claim, the question would arise: will it get through and will I be reimbursed? To date, they have had a piece of paper to submit, concrete evidence of a claim due.

In outlining the concerns pharmacists have, I believe we may have set out the criteria essential for a suitable electronic terminal. Such a device should be capable of either serving as a self-contained unit or be capable of direct on-line communications with remotely located computer facilities. It must be economical to operate, easy to use, provide immediate patient validation if required, occupy a minimum of space, be flexible and require, at the most, minor modifications in the current professional procedure for dispensing prescribed medication.

The arguments for and against such a system will probably go on for awhile and no doubt other advantages, and disadvantages will be brought out at this conference, but the application of computer technology to pharmaceutical practice does present a challenge, one that will have far-reaching implications.

A MANUFACTURER'S VIEWPOINT

Thomas M. Collins
Vice President, Smith, Kline and French Laboratories

Years ago, I was given the assignment in my company to look into the likelihood of out-of-hospital drug coverage for the over-65 and the effects it would have on SK&F's markets and methods of doing business. As the most frequently requested extension of Medicare, drug coverage seemed to be a certainty from a political point of view. And it was clearly in our best interest to see how drugs would be covered from a public health, as well as an industry and government, point of view.

In the intervening years, we have been through some interesting struggles among industry, pharmacy and Congress over how drugs should be covered -- not only for our senior citizens, but for all those covered by other types of third party payment programs. So, whether you now take the viewpoint that one billion or two billion prescription bills will be paid for by the federal government shortly, the following seems completely clear. To process so many prescription claims at a small unit cost will require one of the most sophisticated computer-based information systems anyone in the health care business has ever envisioned.

Let's assume that out-patient drugs for the over-65 will be a reality by the late 1970's. This means the government, directly or indirectly, will be paying for approximately 45% of the pharmaceutical products produced by U.S. drug manufacturers. The pressure on Congress and the government to provide out-of-hospital drugs have been evident since the implementation of the Medicare legislation in 1966. We have had study groups all the way from the HEW Task Force on Prescription Drugs to the recent Flemming Commission report prepared for the Nixon Administration. (This Commission calls for 1974 coverage for the twenty million over-65 who consumed 25% of the industry output.) We should be thankful that with each of these reports, including the fine pull-together of Professor Dunlop and his committee in 1969, we have seen a more rational approach to drug coverage than those proposed in the late 1960's by several labor unions and, more importantly, in Congressional proposals (e.g., the Long and Montoya Bills), that sought to establish all types of restrictions such as rigid formulary controls, annual deductibles and individual patient submission of claims.

While we say the government will be purchasing approximately 45% of the pharmaceutical products by the late 1970's, we must remember this could easily be a minimum figure. It certainly is a deceiving figure when we include the gamut of private third party pay programs that will undoubtedly adopt the same administrative procedures and controls that government programs will use. While most observers feel a major national health insurance system will be one of evolution rather than revolution, we can't overlook the prospect that political pressures may shift drug coverage of these private programs into the government sector as national health insurance plans emerge. So, let's say that the span of government purchases of pharmaceutical products may range from 45% up to coverage of almost total industry output. That should shake you, whether you are a conservative or a liberal.

I still hear many of my friends in pharmacy and in the industry discussing whether or not drugs should be covered under third party payment programs. We all know these programs will definitely change drug care systems and changing the status quo isn't usually a popular idea. Yet the value of debating whether drug coverage on a pre-payment basis is coming appears to me to make little sense. For despite the soundness of arguments pointing out gigantic bills, administrative burdens that outweigh cost savings to the patient, etc., I am convinced that political and social pressures will make extensive drug coverage a reality shortly. Correspondingly, a national drug information network to gather data to handle payment of claims is not only desirable, but is absolutely essential, to avoid an administrative morass that could put pharmacy's and the industry's public image in further jeopardy. So, let us get more directly to the point by skipping from the academic question of need to the functions or implications of a national drug information system. First, some assumptions.

1. By the late 1970's we will have a computer network based on terminals transmitting from the nation's major pharmacies, with large government-funded regional centers processing prescription claims.
2. Pharmacy terminals will do more than just process bills. For example, these terminals will permit data transmission of information on virtually all aspects of the pharmacy business.
3. The network will provide two-way communication between third party payers, drug wholesalers, industry market researchers, etc. and will substantially change the marketing activities of the drug industry.
4. Computerization of inventories will substantially increase the efficiency of stocking, not only of pharmaceutical products but all health-related items carried in our nation's major pharmacies.
5. The biggest single beneficiary from the development of this complex system will be the general public -- if we avoid blundering into so-called cost saving systems that jeopardize the quality of pharmaceuticals and the range of services provided by the pharmacist.
6. Computerization will provide a means to better control drug utilization including patient drug profiles, data on drug compatibilities, and emergencies. Further, this computer system will be of significant value in certain aspects of determining what drug should be prescribed.

You will note that in my assumptions that I used several qualifying clauses. I believe I would be doing the drug care system of this country a great disservice if I did not; for I have even heard some of the people in this room advocating the use of restrictive national formularies, uniform professional fee payments and other so-called cost-cutting devices. I feel such devices would adversely affect the practice of pharmacy, produce a national network of drug information that would be utterly chaotic and provide poor patient care. You may think these are self-serving comments, but it's crucial that their implications be considered.

However, proceeding on the basis that national drug pre-payment programs will develop in an orderly and intelligent fashion, let me speak further on the probable implications of a drug information network based on a sophisticated national computer system.

For the next few moments I'm going to ask you to wear the hat of a drug company Marketing Vice President, as he considers the various opportunities and problems that could result. Upon examination of the potential size of the network required, you might conclude that many of the service organizations now used by your Marketing Research Operations will go out of business. If the government were able to quickly give data to pharmaceutical companies, on their own computer consoles, taken from the nation's pharmacies and stored centrally, I could see our friends at Lea Associates, Gosselin and Company, Cambridge Computer Corporation, IMS-DKK, etc. looking twice to make sure that "big brother wasn't taking over." However, if we can learn from the lessons of other countries, I think it fair to say that rather than be threatened by such a network, if the existing service organizations have adequate access to the government data, they can provide the pharmaceutical industry with even more complete and extensive information than before.

You will want your Marketing Research Director to answer the question of how much information the Federal Government will make available to you or to the service organizations you contract with for data on drug store purchases and prescription audits. The availability of this data to the industry and to the service organizations is a major question that must be answered. Can this information be easily and readily retrieved from a high-volume, nation-wide computer system? Can it be retrieved and massaged (as the marketing researcher would put it) in an efficient and economic manner? Will it be timely, or, as with some government reports, will we have to wait months and even years for the information? And you, as the Marketing Vice President, had better be prepared to not settle for outdated data that won't measure what is certain to be a consistently changing drug usage pattern as drug programs expand.

After you have sent your Marketing Research Director on a feasibility study, you can then ask your Sales Manager what effect this whole effort is going to have on detailing and promotion, to both the physician and the pharmacist. Perhaps you should contact your Systems Analyst to find out how many seconds or minutes the pharmacist will have free from the computer terminal and filling prescriptions to see your detailman. He is sure to tell you that, despite the efficiency of the national drug information network, there is no way the pharmacist can really handle his increased workload, his patient profiles, his inventory situations, his paperwork, his patient consultation duties, etc., unless he has a specially trained assistant who can help perform these functions. After the Sales Manager has determined that the pharmacist is going to be a pretty busy man, he had better be prepared to make his detailman's calls more concise and more effective, both on prescription and OTC products. He will also suggest that you call your counterpart in the proprietary end of the business to tell him what you've learned. You then will probably agree that it will be much more difficult to sell proprietary products and front-of-the-store merchandise directly to the owners versus a "manager of the front of the store." With the concurrence of the Marketing Research Director, I am sure there will be agreement that there will be more self-service items in the pharmacy than ever before. Someone will then quickly point out that this conflicts with the concept of third class of drugs and consumer education in the pharmacy -- covering everything from cosmetics to cold products.

As you look at your Product Management organization, you will want your managers to project what products will be most affected by a national network that is sure to place greater focus on competitive prices, duplicative products in therapeutic categories and, with the treatment of additional millions of people, what new market areas might develop. In defining some of these opportunities, you would have to translate market projections, in terms of increased utilization and new markets, into dollars and cents figures. These figures would help to direct specific research and development programs which could have additional pay-off, as related to those that will be the major chemotherapy breakthroughs in the next decade. The data base will provide the needed marketing research data to give you substantial inputs as you make some crucial product and research and development decisions. For example, never before will you have accumulated so much data on drugs being used for specific indications that have passed peer review, utilization controls and prescription pricing reviews.

Next, you will have to ask your Distribution Director what changes the computer information network will have on product stocking and ordering. Will the wholesalers, as some predict and I personally believe, be able to automate inventory ordering systems to such a degree that automatic stocking on a local basis will make more sense than buying pharmaceuticals directly from numerous manufacturers? You'll have to check into the resultant effects of more efficient buying and ordering as both wholesaler and retailer stocks are lowered. In many cases this will be a one-time manufacturer loss; in others it may have a dramatic effect on both wholesaler and retailer stocking of established and new products. If we are involved in a huge computer terminal system, how will your distribution capabilities match up with the pharmacists' computer terminal system? What cost will you be absorbing for this information whether you are a direct or indirect selling manufacturer?

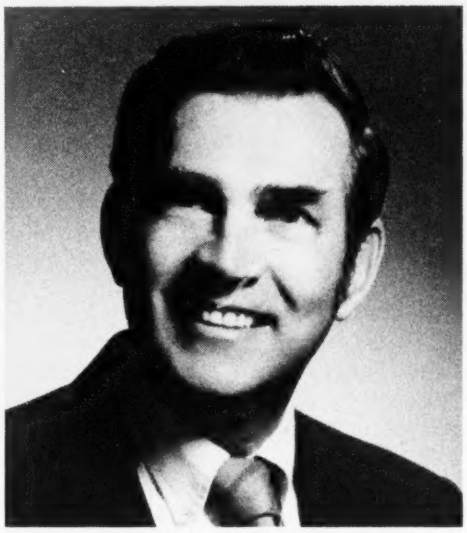
In the beginning of my speech, I asked you to ignore whether or not we're going to have increased drug coverage under government and private third party payment programs. I did so because I wanted to focus my talk on the value and challenges of a national drug information network, from a manufacturer's standpoint. While I'm convinced that drug coverage for the over-65, and perhaps for a much larger segment of the population under a national health insurance system, will become a reality, the questions of when and to what extent will continue to be debated throughout the coming year.

As I've said today, I believe the private service organizations have a stake and an opportunity in any national drug information network. Their challenge is to provide more useful information to the manufacturers, the providers and the government; and it's a considerable one. Today's services will not satisfy tomorrow's needs.

Our own concerns, as we anticipate expanded drug insurance programs, and the attendant national drug information network, tempt us to worry only about our own problems. We've played that loner's game before, on other, less vital, issues -- and we all know what it has cost us. So let's not go that route again. The fact that we are here today proves that we have a common interest. Let's make sure in our future dealings that we realize we have a common goal -- first class health care for all the public.

A THIRD PARTY POINT OF VIEW

William H. Finigan
Vice President, PAID Prescriptions



There seems to be little doubt that third party prescription plans will be a way of life for the practicing pharmacists. A common prediction nowadays is that by 1975 at least 75% of all prescriptions filled will be paid through a third party mechanism. The extent to which each pharmacy is now involved with the third party systems can vary considerably and is subject to immediate change. In October of 1969 when the United Auto Workers program became effective, many pharmacies were found with a high percentage of their business in the third party area that was formerly cash business.

As these programs develop there can be two different directions in reference to who actually receives the payment -- the patient or the pharmacist. The patient reimbursement types have been tried but are now being abandoned in favor of the service programs or sometimes called the pharmacy-vendor or pharmacy-reimbursement programs. The patient reimbursement programs are costly and cumbersome to administer. Also the patient was faced with the problem of having to pay for the drugs, and most often at a time when he could least afford them. If the patient did not have the claim forms or lost his receipts, he might never get his money back. It is not difficult to see why these types of plans are not popular with the patients.

The patients are demanding the service benefits programs -- one where they can enter a pharmacy and receive the drugs that their doctor has prescribed and receive this by the presentation of an identification card. Along with the predictions being made of the high percentage of third party claims for prescriptions by 1975, we also hear comments that most of the claims will be required to be filled and processed through the pharmacy service programs.

As administrators of these service benefit programs, our customers will be primarily governmental agencies, insurance companies and trust funds. These are our customers because it is their funds that we pay to the pharmacies for the services that are provided. This put us as a fourth party in the third party payment system. As such we must be aware of the needs of all three parties with which we are involved.

Patient and Funding Agency Needs

As the patient is the center of attention let us briefly look at his needs. The patient must be informed of the benefits of the plan -

this includes knowing the types of drugs that he is entitled and also those which he must pay for himself. He must know where he can go for service. This should be the pharmacy of his choice, provided of course that his pharmacist wishes to participate. Lastly, he must have some method of identifying himself so that the pharmacist can accept with reasonable assurance that the patient is eligible.

Those agencies that control the finances also have needs, whether it be a governmental agency, an insurance company, or other. Their primary concern is that the patient's needs will be met. These agencies often have staff or outside consultants to assist and advise in the development of a benefit package. Often times they rely on the drug program administrator for guidance in this area. A funding agency is also in the position of imposing restrictions, allowing for special considerations, or otherwise allowing the administrator an amount of professional leeway.

Of primary importance to this funding agency is an administrative system that will protect the financial integrity of the program. That is, the agency must have not only the reports to show where the funds are being spent, but also it must be provided with analytical reports to reveal the developing trends. It is only logical that this type of report should be furnished by the program administrator that is collecting the data.

Pharmacist Needs

The last party to the transaction, the pharmacist, also has needs and this is where I see some of the greatest changes taking place. I realize that the needs of the pharmacy owner and the pharmacist sometimes are not the same, but for purposes here I will try not to differentiate.

One area that no doubt will receive much attention is that of compensation. My personal belief is that one of the greatest needs for pharmacy today is a text entitled, "Cost Allocation and Accounting Principles for Retail Pharmacy." Traditionally pharmacists have kept the cost records that satisfy their requirements for their business. These records may or may not have been kept in such a manner to properly reflect the allocated costs of the various departments of the store. The pharmacist must have a simple, accurate method of comparing his costs for providing professional services as well as for the cost of goods to satisfy himself that what is being offered will meet his reimbursement requirements of doing business. Certainly these programs cannot succeed if the compensation levels are not fair to both the funding agency and the pharmacist.

Second in importance only to the level of compensation is the promptness of payment for claims submitted. The drug program administrator must take the bulk of the responsibility in this area. The pharmacist also has a duty to submit the claims on a timely basis, with accurate and complete data entries.

One method of increasing the pharmacist's compensation is to increase his productivity, by relieving him of the clerical responsibility which seems to have fallen on his shoulders in completing a claim form. I assume one of the purposes of this conference is to take a long look at data recording, how it is recorded, what is recorded and who does the recording. These all revolve around each other and the future is holding many exciting promises. Right now the typewriter and the ball point pen command the spotlight. One of the present problems is the inaccuracy of the data that is sometimes recorded. The use of the plastic card and the imprinter have done much to provide accurate patient and pharmacy data, but humans do make errors in the other fields of information that must be recorded on each claim.

The ultimate in sophistication is a computer-linked device in the pharmacy, and possibly in each physician's office, nursing home, hospital, etc. Such devices are now available and a major unresolved question is whether the costs of having such a device "on-line" to a computer will be justified by the benefits derived. An on-line system will be tremendously expensive, but if the costs are split among many agencies the share for any one might be manageable. There are areas to be explored in such a system that are not related to the costs, such as protective devices to insure the confidentiality of data, and the legal responsibility that may arise for the commission or omission of an act that comes as a result of having access to data banks that would be an integral part of an on-line system. I cannot even begin to scratch the surface — hopefully, this is the objective of the conference, to examine all aspects of such a system.

Just a reminder --- Regardless of the sophistication of any device there must always be a paper back-up system that will allow the continuation of the provision of pharmaceutical service when the device or the computer is down.

Utilization Review

The last area that I would like to go over briefly is what is done with the data that is collected to effect better patient care - that is utilization review. An area where we shall see significant advances in the near future due to the influence of third party drug programs is in utilization review -- that is: peer review - pharmacist participation in the promotion of rational drug therapy. As Marcel Laventurier has stated, "We are expected not only to preserve the health, but also to conserve the wealth of the community by adhering to standards which will be of benefit to the total community....."

Time does not permit a lengthy discussion of peer review. However, I would like to make a few comments regarding an active peer review committee that is sponsored by PAID in the San Jauquin area for a Title XIX Drug Program. The basic philosophy under which the group operates is as follows:

A selected group of local practicing health professionals reviews patterns of drug utilization in a program in which they participate. They establish parameters of current practices based on computer reports, determine variances from accepted local standards which should be researched and from this study prepare guidelines of proper drug utilization. By a constant process of review and study, the Committee assumes as its prime objective the achievement of high standards of patient care through the promotion of rational drug therapy. Rational drug therapy was considered by the HEW Task Force on Prescription Drugs to mean, ". . . prescribing the right drug for the right patient, at the right time, in the right amounts, and with due consideration of the relative costs."

The committee has found that there are seven characteristics of a viable Drug Utilization Review process. They feel that the absence of any single one of these seven would jeopardize the process:

1. Local Control
2. Peer Activity
3. Multidisciplinary
4. Scheduled Activity
5. Power to Act
6. Education
7. Legal status and immunity.

Rational Drug Therapy involves the physician, the patient, and the pharmacist. At one of our data centers we do not have a Drug Utilization Review Committee formed as yet. This is a new operation and time has not permitted activity in this area. However, this does not mean that we do not have cases for a review committee to study.

For example, we had a patient who went to three pharmacies and within a period of twenty-three days received the following drugs:

_____ Robaxin
_____ Equagesic
_____ Formatrix
_____ Mepergan

(Tablets in quantity to last 5 months.)

If the patient had taken all of the drugs that she had obtained within this short time span, then she most assuredly has over-medicated and if she was not taking them, she has unnecessarily spent quite a sum of the funding agency's money.

Another illustration might be the following: The average ingredient cost for all prescriptions filled under a particular program is about $2.60 One particular pharmacy has submitted nearly one hundred prescriptions with an average ingredient cost of over $13.00. Needless to say, reimbursement is being withheld as a preliminary investigation has indicated a severe case of hanky-panky.

I pointed out these particular cases because as a third-party drug program administrator I feel we must have a mechanism involving practicing professionals that can review and act on the facts that are produced as a result of computer analysis of the claim data. Under all health care programs there must be a concerted effort to preserve the health and conserve the wealth.

THE PATIENT-CARE VIEWPOINT

Emmanuel Mesel, M.D.
University of Alabama

As the representative of the patient in this colloquium, I would like to begin by quoting the first paragraph of Richard Burack's introduction to his new handbook of prescription drugs.

"A highly respected medical educator (F.W. Peabody) once wrote, 'The secret of the care of the patient is in caring for the patient.' Two or three generations of American physicians, most without ever having known him, have been deeply influenced by his words. We physicians are proud of the quality of scientific medicine in the United States, but many of us recognize that all is not well in our medical-care system. One gravely disturbing problem concerns the quality of prescription writing. Some of us, because we care for patients, are unwilling to sidestep this issue, which is 'controversial' because it involves large sums of money and corporate profits."

The central issue as I see it in our consideration of "the needs for and probable functions of a national drug information system" is the quality of the information we make available about drugs so that rational prescription becomes a possibility. I recently served as a consultant to the director of the Alabama Title XIX (Medicaid) program as a member of a committee charged with making of recommendations for limiting benefits under the drug program. If you are familiar with the NAS-NRC reports on drug efficacy, you will not be surprised that we were repeatedly frustrated in our efforts to find unequivocal evidence for the efficacy of many products, and in the final analysis had to use cost as the basis of some of our decisions. I will have more to say later about how we set priorities for possible deletions from the drug program.

Sources of Difficulties

What I would like to do now is to examine the sources of the difficulties that confront us in seeking accurate information about drugs when we write prescriptions. If the sources of difficulty are not corrected, then no amount of computer technology, artful distribution systems, new manufacturing processes, skillful administration, or utilization review programs will compensate for this lack. We might just as well pack up now, send our computers back to IBM, and go about our business as usual.

Why is it so hard to come by good solid information on efficacy? In simplistic terms, physicians by training have never learned to acquire and to insist on the hard information needed to make the binary decision to prescribe or not to prescribe.

MEDICAL PHARMACOLOGY

An integrated course of lectures, laboratory exercises, and conferences designed to present the fundamental aspects of the actions of drugs. Emphasis is placed on therapeutic agents, the rationale of their use and their toxic effects. Prescription writing and toxicology are included in the course.

Source: UAB BULLETIN 1970-1971

(Slide 1)

This is the course description of Medical Pharmacology at the University of Alabama, Birmingham (U.A.B.). If you study it critically, you will find that nowhere is there a reference to involvement of the student in an actual, real-life clinical drug efficacy study. Some of the blame for our present difficulties must therefore go to our centers of medical education. How is a medical student, and subsequently an intern or resident or practitioner ever going to learn how difficult it is to judge the efficacy of such drugs as analgesics and psychoactive pharmaceuticals unless he learns from personal experience in an on-going program of clinical drug evaluation? Unless he learns these techniques early in his training he is unlikely to apply them to his own clinical practice. Reading about double-blind studies and then evaluating the effect of drugs on a half-dozen patients makes about as much sense as reading about open-heart surgery and then attempting the procedure without careful supervision and long years of learning experience. Too often what passes for clinical therapeutics is the uncritical adoption of the opinions of the local "authority"- whether that person is the next in the pecking order or a professor of medicine. The blame for what we observe in actual practice must also be shared by the drug industry. Taking advantage of the physician's lack of preparation in critically evaluating drugs, the manufacturer bombards him with a continuous barrage of unbalanced and frequently misleading information and reinforces his belief that he himself can evaluate drugs on his own patients through the medium of the detailman Having once relied on an authority-figure for basic therapeutic information, the physician is all the more ready to transfer to the detailman his need for another authority when he goes into practice.

TOP 10 DRUGS - 1970

1 DARVON COMPOUND 65
2 INDOCIN
3 LANOXIN
4 SER-AP-ES
5 ORINASE
6 ANTIVERT
7 PAVABID
8 LIBRIUM
9 VALIUM
10 PHENOBARBITAL

(Slide 2)

Ten Top Drugs in Use

Above is a list of the ten top drugs in the Alabama Medicaid Program in 1970. I'm sure that the list is no surprise to industrial representatives, to government and insurance administrators, and to most educators in pharmacy or medicine. What surprised us most was that Indocin was the second ranked drug; not only by units dispensed but by cost as well. Considering the fact that it is not the first line of defense against the limited number of conditions for which it is indicated - i.e., rheumatoid arthritis, gout, and osteoarthritis of the hip, I can only attribute the wide use of this drug to the tremendous amount of promotion it has received in all the major medical journals and giveway's.

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in active stages of moderate to severe-
ankylosing spondylitis
rheumatoid arthritis
osteoarthritis of the hip

PAIN
TENDERNESS
SWELLING
INFLAMMATION

are often relieved by...
INDOCIN
(INDOMETHACIN MSD)
-after an adequate trial of aspirin and rest

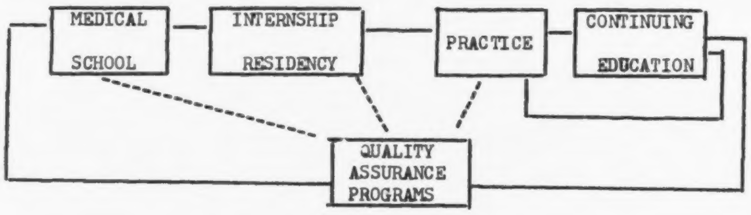
(Slide 3)

I would like to call your attention to the small type at the bottom of this illustration taken from a recent issue of the Medical World News. Indocin is recommended only "after an adequate trial of aspirin and rest." Since the Alabama Medicaid Program provides recipients with OTC as well as legend drugs, you might expect that aspirin would be found higher in the rankings than Indocin. In actuality, aspirin was not even on the top ten list. The following is a comparison of Indocin and Aspirin for 1970:

	INDOCIN	ASPIRIN
Units Dispensed	2.4 million	.55 million
Cost	$286,000	$17,000
Number of Transactions	$ 44,000	$ 7,000

Bear in mind that aspirin is indicated for many more conditions than Indocin, but despite this fact the total number of transactions for Indocin is six times greater than for aspirin. We are currently engaged in an intensive study of Indocin since our suspicion has been aroused that it is being used promiscuously.

When I mentioned our observation on the large scale use of Indocin to one of my clinical pharmacology colleagues at U.A.B., I got a typical "you must be kidding" response. The reason my pharmacologist friend was surprised is a particular case of a general phenomenon: medical education being essentially an open-ended process, the outcome in practice rarely influences the input to medical curriculum planners. The problem is all the more acute because teaching is now more and more in the hands of "full-time" faculty who may be completely oblivious to what goes on in "private" practice.



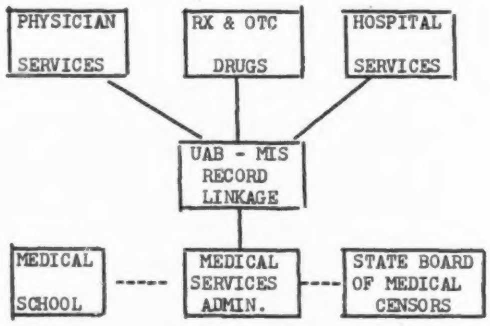
(Slide 4)

The cure, in part, is to close the loop by providing feedback pathways (the dotted lines). In the traditional, or open-ended, system of medical education, the student is taught pharmacology in his "basic science" courses, progresses through clinical clerkships, internship, residency, and finally into private practice. The choice of "continuing education" courses, if attended at all, depends upon the practitioner's own impressions of what he needs to learn more about. If the loop is closed so that medical educators are kept informed of what actually occurs at each level of practice, then courses can be geared to the needs of the real world. The same information could also be used in counseling practitioners on the need for remedial courses.

Need for Information Feedback

I think that one of the major functions to be served by a national health information system, of which a drug information system would be a part, would be to provide such feedback pathways from practice back to the medical schools. Curricula could then be modified in response to what is being observed in practice. If particular problems concerning the use of certain therapeutic agents were found, then appropriate changes or a shift in emphasis could be made in the teaching of pharmacology; perhaps additional attention might be focused in other courses on the various disease processes for which these agents are appropriate or inappropriate.

Along these lines, we at U.A.B. have been very fortunate to have the opportunity to build an information system to link what occurs in practice in Alabama with the School of Medicine.



(Slide 5)

In cooperation with the Medical Services Administration and the State Medical Association we are implementing and operating a health data system (U.A.B.-Medicaid Information System) which is quite similar in concept to the Oxford Medical Record Linkage Project in England. Recipient profiles are constructed from Medicaid claims information originating at points of service by providers in physician's offices, laboratories, hospitals, nursing homes, and pharmacies. The information includes diagnoses, medical, surgical, and laboratory procedures, and drugs dispensed. All these ingredients of a complete patient profile are received in machine readable form from the various intermediaries in the program. The profiles cover 350,000 people - 10 percent of the state's population and performance characteristics on two-thirds of the state's practitioners. Although the information we receive may seem trivial at first glance, the linkage of all transactions for a given individual can provide us and program administrators with keen insight into the practice of medicine and its quality. As a concrete example, if someone were taking an anticoagulant drug, and did not have periodic prothrombin determinations to test both for the efficacy and safety of use of the drug, one could say out-of-hand that that patient was not getting good care. One might use this information for various purposes: to educate offending physicians, or if a sufficient number of these inappropriate acts were discovered, perhaps to offer a special course, and to emphasize to students the proper handling of this group of drugs.

As I indicated earlier, we are currently using this data base system to study the probable misuse of Indocin. In the process of doing so, we have developed a general model based on package-insert information for drug utilization studies that can throw considerable light on the quality of patient care. For each drug this document lists a set of indications, contraindications, and possible adverse reactions. Many of the adverse reactions are detectable only by diagnostic laboratory tests (e.g. leukopenia). Thus for any drug one can formulate a series of logical relationships among drugs administered, diseases present initially, diseases subsequently encountered, laboratory tests performed (or not), and the need for hospitalization or other special services, and then retrieve the cases meeting each specification. Obviously the worst case would be the administration of a drug to a patient with no indication for its use, with a major contraindication, and the occurrence of a major reaction. We have already encountered numerous such examples.

The need for local, regional, and national health information systems has been amply demonstrated by the speakers that preceded me. The expansion of medical knowledge since World War II has made it impossible for any physician, no matter how thoughtful, conscientious, or endowed with memory, to remain current with advances in his own specialty area much less in the general practice of medicine. We have also witnessed in the last 25 years a transformation of the delivery of care by a marked shift from solo practice to the formation of groups of ever-increasing size. As Dr. Lawrence Weed, of the University of Vermont in Burlington, has emphasized, the patient, who is not infrequently also a taxpayer, is the innocent bystander, the passive agency whose course through the growing labyrinth of the health care system must be expedited. Just because the physician is human is no reason that the sick or the worried-well should suffer. Good patient care demands that all physicians involved in a case have access to complete medical records.

Concept of a System

At the risk of being repetitious, I would like to present my concept of a national drug information system and the conditions that have been imposed in designing it. I have taken a "best of all possible worlds" approach assuming that there will be no technical or economic barriers to creating such a system and that those who use the system are ideal pharmacists, physicians, administrators, and manufacturers. As a physician, I am sure it would be too much ever to expect to see a population of ideal patients - but that may be a reflection of the less than ideal performance of the rest of us, and I certainly include physicians in the latter group.

I have assumed that the drug information network is a subsystem of a general health care information system, and as such, it will be well to remember that the optimization of a complex system is not necessarily assured if the component subsystems are optimized individually and designed without regard for the interrelationships among the several parts. In designing this network, I am also assuming that cost optimization will be secondary to the optimization of the quality of care. Good care is not necessarily expensive on the average, but may be extremely costly in individual cases. Thus my view of a national drug information system and network would provide terminal facilities in physicians offices, in pharmacies, hospitals, medical educational institutions, manufacturing establishments, in administrative and insurers offices linked on a priority basis and with proper safeguards for the confidentiality of information to a central data base.

I see as a major function of a drug information system the provision of a clinical profile of the patient. This would include a problem list in the Weed sense - that is, a list of the various symptoms, laboratory test abnormalities, diagnoses, etc. that need managing - the status of each of these problems, what has been done in the past to manage each of these problems, diagnostic procedures and their results, and a complete summary of drug management.

Additional functions to actively assist the physician to practice rational medicine will certainly be required. These too have been discussed by the previous speakers and there is a growing body of literature on the general subject of clinical support systems in the professional journals of pharmacy and medicine. I will sketch some of these functions but not dwell on each one at length:

(1) Primary information to the physician would include the major indications and contraindications for the use of each drug. Sophisticated systems might actually display a list of medications and their order of preference for each of the patient's problems.

(2) Dosage schedules including preferred single doses, route of administration, and duration of therapy.

(3) Likely interactions with other medications being given the patient, and perhaps a list of symptoms to be particularly careful in checking for. A list could be generated and given to the patient to alert him to possible difficulties.

(4) A means of recording the amounts actually taken by the patient - this could come from the patient's home via simple telephone devices already available.

(5) Lists of diagnostic precedures to be performed by the physician to monitor the drug for desired effect and for safety in drug use.

(6) The collection of a data base of sufficient depth to support intelligent utilization review, and to make quality assurance programs possible.

(7) The capacity to close the feedback loop between actual practice and medical school curricula so that teaching priorities have some basis in the real world.

Since I have been assigned the special responsibility to present the patient's care viewpoint, I would emphasize that provision must also be made to educate the general public about drugs and that this ought to be given equal priority with the "professional" functions directly related to physicians and pharmacists. Consider for the moment the number of drugs available over-the-counter, the way these products are promoted through the public media, TV notably, and the volume of such products purchased and consumed, and I believe the folly of restricting our interest and attention to prescription agents alone will be immediately apparent. I will forego any lengthy comments on the relationship between self prescription of OTC and legend drugs by laymen and their children and the present national disaster of drug abuse and addiction.

In closing, I would like to emphasize that all will be for naught if the quality and accuracy of the information on drug efficacy in the drug information system is short of excellent. I have already emphasized that changes in performance will be required by all concerned with the production of this information. The drug industry alone is not to blame. We, as physicians, pharmacy and medical educators, FDA and other administrators, manufacturers, insurers, must do what is necessary to improve information on efficacy. To prescribe or not to prescribe is a go -- no go decision. To prescribe a product that is only "possibly effective" is intolerable.

I think we must do what is necessary to improve the information on efficacy, at the expense of the collective pocketbook if necessary. This may mean foregoing profits, reorienting academic interests, or providing adequate tax appropriations -- without it all the glorious technology will accomplish nothing.

2. SYSTEM DESIGN CONSIDERATIONS

Donald C. Brodie, M. D.

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WORKSHOP DEFINITIONS

Erwin Danziger
Director, Administrative Data Processing
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Good afternoon. I first want to acknowledge the presence and assistance of my fellow consultants for this session. They are Dr. James L. Carmon, Director of the University of Georgia Computer Center; Miss Winifred Sewell, of the University of Maryland, who is completing her term as president of the Drug Information Association; Dr. David R. Work, Assistant Dean of the University of North Carolina School of Pharmacy, who is also our legal adviser; and Mr. Paul de Haen, who produces the Drugs-in-Use Index. With such a wide range of expertise, we will try to field questions you may have.

Our purpose at this time is to lay the groundwork for the workshop sessions by reviewing some definitions and guidelines pertinent to our forthcoming discussions.

This morning you heard comments on some of the roles electronic data processing might play in health care delivery and specifically, in the practice of pharmacy. You heard about the probable need for a national drug information network. This afternoon, there will be four (4) separate, but concurrent workshops where we hope you will explore some of these concepts in more detail and bring your practical experience to bear on these questions. I urge you to concentrate upon the specific needs and the requirements for information records for each workshop area and how computer-based systems can - or cannot - fulfill them.

For the next few minutes, I will try to give you some specific problem areas that you might wish to consider and then, we will see a short film defining some of the words that you have heard and might hear. In addition, since proper semantic word usage can often be of help in increasing communication, we have provided you with the little glossary produced by Newsweek magazine. Also the Life educational reprint, "How the Computer Gets the Answer", is an excellent summary - which I strongly encourage you to read.

Now, having used the word "computers", let me hasten to point out my personal viewpoint that computers generally have been oversold to the public at large. A computer is an inanimate machine and, like a very fast adding machine, can be unplugged by people.

It is people who develop input data for computers.
It is people who give the detailed instructions to the computers.
It is people who use the output from the computers.
And it is people who often misuse the computers.

The computer by itself is just a hunk of junk metal. It can do nothing, absolutely nothing, by itself.

Television shows and movies like "2001" to the contrary - a computer cannot think, cannot reproduce itself, cannot love, hate, or appreciate beauty or truth. It is a relatively simple machine.

Computers are usually used to manipulate data (or facts about something). These data elements or items or facts can be collected about a drug, a patient, a pharmacy, or a doctor. When these data elements are gathered about one thing, a drug or a pharmacy, we call this a record and usually identify this record with a unique identifier, normally called a key. A collection of records about an associated group of drugs, or patients, or whatever, is called a file. In computer systems, files of data are usually stored on magnetic tapes or random access devices. Master files of data records are relatively permanent, normally containing quite a bit of information about a drug, a patient, or a doctor. Most of this permanent type of data is usually gathered and included in the master file record when the file is first established. However, some of the data in the record will change over time and additional data may be added. This is called updating the file or file maintenance. The data records used to update the master file are normally called transactions, and represent the changes and/or additions to the master file records.

An information system of an organization is simply the pattern of data flow and data processing operations. A communication network might be used to connect, via telephone or microwave lines, terminals to computers and computers to computers.

The computer is an information handling tool in the information system - it is only important in respect to the information system that it supports. A terminal can be thought of as a remote appendage to the communication network, through which one can enter or receive data, or both.

The computer is really nothing but a collection of nuts, bolts, wires, and electrical circuits over which data and instructions could travel.

A computer system is a collection of these nuts and bolts devices, which when connected together and correctly instructed, could process data for the information system of the organization. This collection of metal wires and boxes is collectively referred to as hardware.

Two aspects of a computer system that make it different from other information processing tools:

1. It's fast - it has electronic speed.
2. It has a reasonably perfect memory - into which both instruction and data can be stored. A computer program is a complete set of instructions to accomplish one function or job.

Instructions have to be painfully and carefully written, one by one, by a programmer. The programmer is told what to program by a systems analyst. The total collection of programs that are available to a computer system are known collectively as the software.

In your deliberations this afternoon, please distinguish carefully in your mind the kind of data elements that would go into the master file record once, or at least very seldom; and the type of data element that would be entered quite frequently - like, for example, each time a particular drug is dispensed. All transactions, of course, must also have an identifying "key" data element so that they can be matched to the corresponding master file record during the update.

I suggest to you that you might first wish to define the master file record data elements sometimes known as fields - breaking these into two groups - required elements, and desirable elements. Obviously you cannot define any master file data elements unless you know, approximately, what kind of useful information and reports you need to prepare using such data. Then you might attack the problem of "Can these data elements be gathered? How? From what source? And, in what way?"

Some of the data could, of course, come from other existing information systems. For example, could the name and address, sex, telephone number, etc. possibly be picked up from the medicare carrier's systems? The linkage key might be social security numbers.

This should then bring us face-to-face with the main problems of data files - and that is - how do you keep these files accurate and current, (timely)? The best answer to that is to try to build some type of feedback loop into your system. Let the people who provide the data know - if it is right or wrong, current or obsolete.

Another problem you will eventually discuss is, how do you build your initial master file records? How do you get the permanent, relatively fixed, data? Some systems collect this data only once, while other systems might collect such data over and over again, despite the high cost of so doing. Building the initial data base often costs 20% to 50% of the total cost of the operating system.

And, finally, how do we collect the transaction data? Do we consider some form of source data automation, that is, can we collect the desired data, in machine readable form, at the site of its origination and, if possible, as a by-product of some necessary business function?

Source data automation (SDA) techniques can be applied when one or more of the following conditions apply:

(1) A significant volume of data is to be handled
(2) There is repetitive use of the same data
(3) Excessive errors in data handling exist, and
(4) Processed data is needed sooner than it can be prepared manually.

There are three basic reasons why data should be captured at its source in machine readable form, whenever practical:

(1) To minimize the need for further manual handling and transcription of the data, thereby eliminating the errors that invariably result from these operations.

(2) To allow as much of the normal processing (such as a billing operation) as possible to be done by machine, and also allow further processing that may be practical only by machine - such as sales analysis.

(3) To take advantage of potential savings in time and money.

Source data automation equipment currently in use, centers around ten classes of equipment, most of which could be used for normal transaction recording purposes -- and as a by-product produce machine-readable output. These are the following:

(1) Automatic typewriters -- including flexowriters and IBM's MTST.
(2) Adding and accounting machines equipped with paper tape punch, card punch, a stylized type font, or magnetic stripe.
(3) Cash registers -- similarly equipped. This is developing into new "point of sale" equipment just coming on the market.
(4) Embossed card imprinters -- like gasoline credit cards.
(5) Prepunched tags -- like Dennison or Kimball tags.
(6) Portable data recorders -- output into punched cards, or magnetic tape cassettes.
(7) Industrial data collection equipment like standard register's source record punch and IBM's model 1030.
(8) Optical scanning equipment is not, strictly speaking, source data automation but often precludes the use of more specialized source data equipment by reading ordinary typed, handprinted or pencil-marked documents. Optical scanners fall into three classes:
    (a) Mark readers, which read pencil marks.
    (b) Bar code readers, which read printed or imprinted bar codes.
    (c) Optical character readers, which read typed or handwritten characters.
(9) Magnetic ink character recognition equipment (MICR) is like OCR, but reads specially-treated inks. The account number on our personal checks is an example.
(10) Cathode ray tubes (CRT) for on-line (often conversational) type of keyed input.

One example of a potential source data automation application is the one suggested for possible use in pharmacies, "The Pharmacy Claim Form." Under the leadership of Dr. Ralph Engel, Director of the National Pharmacy Insurance Council, a study of basic data elements desirable for a third party claim form, has led to the development of a three-part snap out form usable with relatively inexpensive imprinters.

Although in our workshops this afternoon and tomorrow we will be looking at computer usage, and other technologies, we should remember this final thought. I quote from a paper recently given by Miss Barbara Murray, of the National Cancer Institute, "The major difficulties which arise in the use of data processing with computers are often not those of technology, but those of human understanding, communication, and cooperation".

2. SYSTEM CONCEPTS

DATA PROCESSING IN THE PRACTICE OF PHARMACY

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I would like to open with a disclaimer. The disclaimer is that I am not a pharmacist, not involved in the practice of pharmacy, not a data processor, nor involved in data processing. I am not involved in research on any of the subjects involved in this seminar. I am not speaking officially for Merck or for industry. So I'm really wondering how in the world I got invited. As near as I can see, it was because in another incarnation some ancient time ago I worked on and attempted to develop a system, a complete information computer system, aimed at computerizing a whole branch of science. It was aimed at the problem of computerizing organic chemistry. There were certain cardinal rules we followed. One of them was not to change the relationships between the then-existing manual contenders and the final computer system; in fact, we were very careful to try to avoid changing those relationships. We just tried to do it better.

What worries me in the Conference that I have heard to date is that I hear relationships being changed. I am going to come to the subject of my topic which is "Data Processing in the Practice of Pharmacy"; and I do think it is an exciting area. I think pharmacy is an area where a lot of novel and important advances in medicine amd medical care can be made. But I am concerned, and I want to speak about my concerns first in order to set in perspective the positive recommendations that I want to make.

There are three subjects that worry me in this Conference which may result in overlaps and confusion. The confusion comes with the purposes of the various systems which are proposed. First, there is the problem of payment. Second, there is the problem of the existing or future role of pharmacists. I detect some uncertainty as to how their role will evolve in the future. Lastly, and perhaps separately, is the question of Utilization Review. These three subjects are at once overlapping and different.

Let's talk for a moment about payments. If it is just processing paper, all kinds of paper processing techniques are going to come along. It can be done the way Mike Ripsman has done it. At the yesterday afternoon session he described how he processes paper with a conventional group of girls at a cost of 25¢ per piece of paper. He has an effective program and since he keeps 1100 pharmacists in good shape, the program is big enough to be a valid experience. It is a very prosaic system but one which the computer people will have a hard time beating. Joe Higgins of the Social Security Administration is talking of new equipment to facilitate the input problem; there is undoubtedly lots of new equipment which is going to come, new techniques are going to be developed, and new memory cores will reduce memory cost. Such a system could be superior provided someone is interested in paying for the processing of the enormous files. Surely this Conference should not get confused on the problem of a mechanical system versus all the other questions on advantages or disadvantages of the roles of pharmacists and the role of the Utilization Review. Pharmacists have to process paper. For heaven's sake, let's give them a good paper processing system and set that aside as a separate and independent subject from the question of the role of pharmacists and the role of the Utilization Review.

Interaction With Physicians

When it comes to the role of pharmacists--here, in a sense, I am on the most shaky ground. I am not a pharmacist. I do not really know about pharmacy; but I do think about it a little bit. Pharmacists--as near as I can discover--from time immemorial, in addition to other functions, have been involved in drug control. They have been involved in record-keeping, and they have been vital in record-keeping. The new concept of the family records is very exciting and is a very responsible role. And most important, pharmacists have been in the habit of checking back with physicians. Even now, pharmacists check back on the phone--"Is this right, do you really mean to prescribe one ounce, twice a day?" The pharmacists' problem is that 80% of the time they are so busy behind the counter pouring drugs out of one bottle into another bottle, writing the label, and doing the paper work, that now the girl out front on the cash register is handing out the medicine. The so-called patient-pharmacist relationship--or for that matter, in the big city, even physician-pharmacist relationship---is evanescent. It is not true in the country. In the country, the pharmacist knows what "Doc Brown" prescribes for everybody.

The systems, as they are now proposed, involve the pharmacist looking to the computer system for his guidance. Standards are to be built into the system to guide him professionally. If the pharmacist is to be considered a professional, then the system must facilitate his dialogue with his professional partners, the physicians; if the pharmacist is considered to be non-professional, then orientation to the computer system is appropriate. The designers of the computer systems seem to prefer orientation to themselves. On the contrary, I would like to suggest that any system which is established be structured to strengthen the professional role of the pharmacist rather than weaken it.

The last Conference subject that worries me is the Utilization Review, and this relates directly to my view of the future of pharmacists and their role in medical care. We have at this Conference representatives of pharmacists, industries, schools of pharmacy, various government agencies, Food and Drug Administration, HEW from the overall point of view, but no practicing physicians. However, the Utilization Review is a review of whom--if it not a review of physicians? Are they needed reviews? Physicians need help; they're a very busy profession, but the role of the pharmacist checking back with the physician has not been heretofore emphasized in this Conference. I am an M.D., and although I am not a practicing M.D., anymore than I am a practicing data processor, it is the championship of this pharmacist-M.D.-patient relationship that I want to stress. Let's come to the future of pharmacy, as I see it.

Let us not view that future as one of a better forms-processor. Let's view it as a profession which, with data now within its grasp, substantially aids the practice of medicine by input of information on the use of medicine.

The corner pharmacist is a part of the action. He is in the third-party payments process. He's pushing the idea of keeping records by family name. The little consoles that the pharmacists are struggling with are designed to help him control inventory, to help him keep his family records, and they ought to help him relate to the M.D. The task before us is to develop a system that will enable us to extract data on drug use, so that the traditional record-keeping function of the pharmacist for his own purposes is broadened to serve the needs of medical practice.

In hospital pharmacy the opportunity for useful data is opening up through the unit-dose concept. This is one subject which has really caught my eye, and which I think represents the way of the future. Its main advantages, which you already know, are worth repeating. It is accurate and cuts down medication errors enormously; hospitals can run 10% medication errors. It also saves nursing time. Why do we want to save nursing time at the expense of pharmacist time? Nurses are scarce and presumably not as well trained as pharmacists in drug distribution. Pharmacists have traditionally distributed drugs to patients. If there were only those two grounds of accuracy and nursing time, the unit-dose concept would become more popular. But going beyond this, I don't think that those reasons are the cause of the excitement associated with the unit-dose concept. For the first time, the patient's name is coupled with the medication record at the hospital pharmacy level. Previously it was on the chart; the physician knew it, the nurse knew it, the pharmacist did not know it. The coupling of the name with the patient record has occurred not only in the hospital pharmacy but also through third-party payments. The coupling of the name with the medication is the conventional way in which medications are judged. The medication record is the proper place to get the medication history. If our computer methods are so designed, pharmacists with their essential records can now participate in addressing themselves to the problems which we face throughout medicine. Therefore, before further discussion of the role of the pharmacist in the future, I think we ought to state briefly what the problems are in medicine.

Where Pharmacists Can Help

What problems do we face? And, if the pharmacist can participate, what can he add? Figure 1 summarizes a conventional list of problems--medication errors can be reduced by the unit-dose concept as discussed above.

A. The risk/benefit ratio is very important. In one sense, I think we are still mired in the past. The Kefauver-Harris Act stated that we had to show utility of drugs, i.e., their benefits as well as the fact that they were safe. However, the regulatory agencies have built up a big adverse reaction file and continue to focus on the risks. But what is the benefit? Nobody really knows. In the final analysis, we don't really know many things about clinical use and experience with drugs. Let us take otitis media. Virgil Howie from the University of Alabama has just published a beautiful report showing that if you use an inferior medicine or if you delay treatment, you get better results than if you intervene immediately with a good antibiotic. Presumably, the reason for this is that the patient has built up a resistance to the polysaccharides and therefore has a lower recurrence rate. That is the only study of its kind in the United States--we have been seeing red ears since the mastoid operation days of the nineteen twenties. The designers of the computer systems talk of standardization of treatment. Standardization without knowledge is easy, but is it right?

Another example is smoking. Smoking is a hazard as shown by broad-spectrum epidemiology. Such broad-spectrum epidemiology is subject to errors and will not replace specific studies, but it will help formulate the need for specific studies. Epidemiology can provide the socio-economic worth of new products. As yet another example, consider the diabetic drugs for the regulation of blood sugar. This problem leads into the question of whether these systems can be used to approach the risk/benefit question. Such an approach cannot be made if we are standardized on the "best" medication. From the nineteen twenties we have known that the control of blood sugar may not change the incidence of complications. The NIH has just finished supporting a perspective study over a ten year span. It is a fine study; but there is a big debate as to whether this study was done correctly. Did it, or did it not, mean anything statistically? Do you have any idea of the number of patients involved in this ten million dollar study? Only one thousand! In today's Conference we are talking in terms of billions of claims. We are talking of pharmacists having records of who is on what medication. Granted, the analysis of efficacy would be crude epidemiology and at the very broadest level, but we might be able to gain some insight into "socio-economic utility." The Federal Government through the HEW and the independent states fundamentally have within their systems this risk/benefit ratio data. They must get those data out if they are going to help advance to better medication. They must compare locality by locality in order to compare the different practices which exist. In diabetes, for example, the Joslin Clinic which is very influential in Boston, may have initiated different practices in New England which could be compared with those in Michigan. Why standardize when you do not know? Why not analyze? They have the data, and I seriously wonder if they should build new systems if they can't handle the existing data systems.

As Gosselin stated the problem in his seminar, the government will be so busy processing claims (life insurance companies may be the same) that is all they will be doing--processing claims. I hope medical data can be obtained before standardization.

The Drug Faithfulness Problem

B. Drug faithfulness is a big problem. For example, consider Rammelkamp's report on children who have rheumatic fever and are on penicillin to prevent a recurring attack of a potentially fatal disease. These children come back to the Clinic because they have existing cardiac disease. Not all of them are motivated to come back; but of those who do come back, only one-third have a blood level of penicillin when you use the long-line penicillins which are easy to detect for long spans of time. And it is their heart. Another example is the difficulties in the central cities with immunization for rubella. Many reports in the literature exist on the failure to have prescriptions filled. The computer systems which have been discussed have emphasized procedures to control cheaters, the dishonest pharmacy, patient shoppers and physicians who do not know how to practice medicine. The lack of drug faithfulness may be more significant than all the dishonest procedures which the proposed systems are designed to prevent. Perhaps the pharmacist and his new order of record-keeping could also help us get at the phenomenon of "drug faithfulness", or more pertinently drug unfaithfulness--the failure of patients to actually get on or use needed medication.

Drug Interactions

C. Lastly, I want to come to drug interactions and drug control because here I think hospital pharmacists can participate professionally. Anticoagulants are now prescribed on the basis of effect, e.g. maintenance of the clotting time rather than a given dose. The availability in hospitals of drug levels and patient names will extend this concept especially for those drugs subject to individual genetic variation.

Figure 2 shows Elliott Vesell's study on identical and fraternal twins. Phenylbutazone blood level changes as a function of duration of administration. No other drug is being administered. The identical twins come out identically. The same individual man repetitively also comes out identically, just as with the twins. But different people (genetically different) vary by a factor of two in the blood level. That is a real genetic difference. The pharmacist will have to be connected to the clinical chemistry laboratory to adjust the proper dose.

Figure 3 illustrates the interaction of nortriptyline and dicumarol---a well-known interrelationship. Hopefully every pharmacist, pharmacologist and physician here knows of this relationship. There is a fivefold difference in the blood level of one out of six patients tested. Another case has a threefold difference. I suggest that these proposed Drug Utilization Review committees that are being set up will contend that the physician was making a mistake by giving 5X the PDR dose or 1/5 the PDR dose. According to Bob Moser, 15% of all hospital patients are on ten or more drugs. In some studies 12% of hospital patients have a drug reaction. There is a role for the active participation of the pharmacist along with the physician and the clinical laboratory and for flexibility based on the individual patient result.

1. Risk/Benefit

2. Drug Faithfulness

3. Drug Interactions

4. Drug Errors

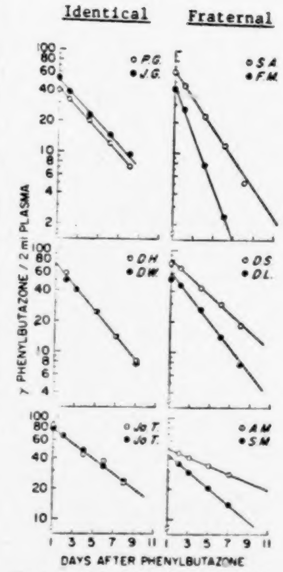


Fig. 1. Decline of phenylbutazone in the plasma of three sets of identical twins (left) and three sets of fraternal twins (right). The log of the phenylbutazone concentration in 2 ml of plasma is shown at intervals after a single oral dose (6 mg/kg).

Science, 159, 1479 (1968)

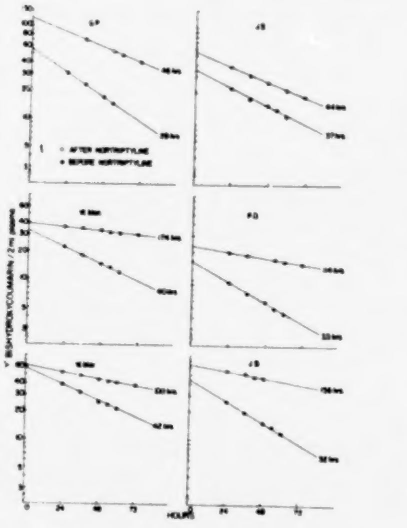


Figure 2. Prolongation of the Plasma Half-Lives of Bishydroxycoumarin in Each of Six Volunteers after Eight Days on Nortriptyline

The New England Jrl of Medicine
E. S. Vesell, et al
283 (27), 1486 (Dec. 31, 1970)

Autonomic Drug Interactions

Drug	may interact with	to produce
Central Acting Relaxants		
Carisoprodol	Meprobamate and others	decreased effect of meprobamate via enzyme induction
	Barbital, phenobarbital, chlorcyclizine, diphenhydramine	decreased effect of relaxants due to enhanced metabolism via induction
	Monoamine oxidase inhibitors	enhanced relaxation via enzyme induction
Chlormezanone	Liver function tests	
Chlorzoxazone	Liver function tests, urine tests	discoloration of urine
Metaxalone	Liver function tests, urine protein test, BSP retention, cephalin flocculation	false positive false positive false positive anemia leucopenia
Mephenesin	5 HIAAA	false positive
Methocarbamol	VMA	false positive leucopenia

Autonomic Drug Interactions

Drug	may interact with	to produce
Peripheral Acting Relaxants		
	Kanamycin, neomycin, streptomycin, polymyxin, colistimethate	prolonged relaxation, reversible or irreversible apnea
	Quinidine	increased intensity and prolonged duration of relaxants
	Procainamide	potentiated effect of succinylcholine
	Thiazide diuretics	"persistent curarization"
	Non-depolarizing Relaxants	
	Anticholinesterases (including certain insecticides, eye drops)	antagonized effects of relaxants
	Depolarizing Relaxants	
	Anticholinesterases	potentiated effect of relaxants
	Procaine, lidocaine	increased apnea
Succinylcholine	Promazine	prolonged apnea
Suxamethonium	Trasylol	potentiated relaxant

L. A. Hartshorn, Drug Intelligence 4, 218 (1970).

Figure 4 and Figure 5 lists muscle relaxants. You can see these interact with patient symptomology, other drugs, or with the clinical laboratory including the production of false positives. I don't know anything about muscle relaxants. You may ask how much most practicing pharmacists from a corner drugstore or hospital pharmacy know about them, but with their finger on data of drug usage they can know a lot more. Physicians can use help; they need help. The pharmacist can give it if he has supporting information and information systems.

The Branch Point

With the arrival of these mechanical and third-party payment systems we are at a branch point. Pharmacists are trained in the medical sciences. They can relate back to physicians. I believe they should be aided and assisted in relating back to physicians. And with their new computational equipment pharmacists not only can provide families what they need, not only provide their own inventory, but they can also provide professional drug control and interaction data. What hospital pharmacy is connected to the clinical laboratory to make this exchange of information? There are very few. The professional level of hospital pharmacy practice could be improved.

But we come to the branch point. If the pharmacist is fundamentally going to relate to claims processing, my feeling is he becomes a claims clerk. I do not think that should happen. I think that when we set up these mechanical systems we should look forward to reinforcement of the traditional relationships. The pharmacist does have a professional role. The new mechanical systems can permit him to play that role. American medicine is suffering now partly because the pharmacist's professional role has diminished. Paper handling in government, industry, and insurance programs can always be improved. We have to try to help the physicians who are on the firing lines, not review them. The first feedback from the pharmacist or the pharmacist's system should be to the physician, not to the government, and then indirectly to a local peer physician group. Although one must consider ignorance and cheating, you should not build a system for cheaters. We should build a system to help educate ourselves and to attack the question of what the benefits versus the risks are from our medications. With the complexities of medicines and drugs increasing, the professional role for all is assured. The government's help in assessing the long-term benefits or hazards of these medicines is far more important than their ability to process paper.

A NATIONAL DRUG INFORMATION SYSTEM - PROBLEMS OF DESIGN, IMPLEMENTATION & OPERATION

William T. Ward
Health Applications Systems Corporation

I am quite pleased to be here to discuss with you some concepts and problems in the development of a national drug information system. The scope and complexity of a national drug information system are so vast and intricate that due to the time limitations we have this morning, I can only hope I can cover some of the major highlights and concerns which I have, and which I am sure you have, for the use of computers in the future practice of pharmacy.

Before we start into design, cost, and operation problems, I think it is worthwhile that we review very briefly several of the applications that are frequently mentioned as conducive for a national drug information system. The first major area is, of course, the third party drug payment programs for both public and private drug insurance plans. Presently well over 200 million prescriptions are handled by drug insurance programs. Even without the institution of a medicare out-of-hospital prescription benefit, this item should grow to approximately 500 million prescriptions or 25% of the market by 1975. If the Medicare Part B Drug Program is passed, an additional 25 to 30% of the market, or 400 million prescriptions, should be added to this third party payment claim volume. Certainly, with current levels of administrative fees ranging from 50¢ to $2 for processing a prescription claim, a more efficient, comprehensive and economical system must be developed to handle the significant increase in third party claims. It is quite conceivable that a fully automated computerized system down to the level of the retail pharmacist could reduce this cost to under 20¢ per claim processed.

Another function lending itself to an automated system would be the accounts receivable-billing requirements of the retail pharmacist. Already most of your drug chain stores and large independent pharmacies have a partially automated system to handle this procedure. It is estimated that over 200 million prescriptions and over-the-counter drug item sales are processed on a credit basis. Inventory data is another function which could conceivably be handled by a drug information system at the retail outlet level. Drug usage data could be transmitted to both wholesaler and manufacturer suppliers selected by the pharmacist. Those persons in turn could maintain and operate inventory control programs and automatic re-ordering procedures for their accounts. Complete flexibility in designating suppliers for particular products could be maintained since the pharmacist still must furnish instructions to this system of what suppliers they would select, what inventory levels should be maintained, and what re-ordering parameters should be used by the supplier for each individual pharmacy account. The before-mentioned functions, however, are all related to administrative procedures and are intended to handle them more efficiently and economically.

There is another area which, in my opinion, supercedes all other applications or considerations in justifying a drug information system. Utilization review is that function which could be more comprehensively carried out by using the data obtained through a national information system. Of course, there would be many problems associated with the use of the data collected and the functioning of a utilization review mechanism. Data ownership, per organization, reimbursement levels and confidentiality of data all would have to be worked out before utilization review could become effective on a local or a regional basis. However, without the complete, timely and accurate prescription record information which can be compiled by the system, evaluation and resolution of prescribing, dispensing, and drug use problems will never be successful. Utilization review holds great promise for both improving the quality of patient care and reducing the expense of prescribed medication used in health care programs. Therefore, the importance of making this function efficient becomes very obvious.

Control of drug abuse within the area of prescribed drugs can be initiated by examination of patient, provider, and prescriber records. Indeed, diversion of legend and over-the-counter agents at the wholesaling and manufacturing levels also can be monitored more completely through the data base compiled by the information system. It is even conceivable to have the operating system reference the patients drug history file and to indicate back to the pharmacist when a new prescription or refill is in violation of certain drug abuse parameters or drug incompatibility conditions for the patient, while the patient is still in the presence of the pharmacist.

I could go on on this point and expound in more detail on those functions which I have stated, or other related functions that could benefit from a drug information system, but I think it is sufficient to say at this time that the need is clearly here for some form of a national drug information system. Other by-products of the system could be (1) to increase the pharmacist's productivity in dispensing a prescription, certainly a major consideration in the face of a future critical shortage of professional manpower in this area; (2) provide a more efficient method of recalling drug products; (3) provide a more responsive mechanism for poison control efforts; (4) provide a more effective means of collecting adverse drug reaction reporting information.

System Definition and Feasibility

Now let's go to the two primary questions of this address. (1) What is a national drug information system? and (2) Is it feasible from an organizational, political, and cost-benefit approach? There are, no doubt, many definitions of a national drug information system which you have heard recently. Let me try to capsulate my concept. It is a computerized operating system which uses national standards of prescription record data; which collects this information in an organized, uniform method; which can be used to improve patient medical care; and which services all functionary levels in the drug distribution industry. In other words a computer system devised to provide an economical and efficient method of handling drug information which will benefit the patient, the physician, the pharmacist, the wholesaler, the manufacturer, drug program carriers, and the third party payers.

To answer the feasibility question is a much more complex issue which will not be resolved today. I can only hope that we can explore some of the major issues so that the policy makers on both the public and private side may consider its various ramifications. I do see the need for such a system, but I am, quite frankly, very dubious about the creation of a viable organization that will serve as the catalytic agent to form the structure and develop the cooperation and coordination needed for the start-up of such a system. This lack of leadership is, in my opinion, the most important and difficult obstacle to overcome before the first step can be taken in the development of a standard national information system. Time is of the essence because as drug insurance programs grow in size and complexity, as the Medicaid programs remain fracturalized and become embedded in state operated systems, and as the drug distribution industry becomes more sophisticated in the computer services they offer pharmacy -- all these elements will become more reluctant over time to institute new changes, which may be costly ones, for their developed programs. But, for the time being, let's assume that a viable organization has been created to study the concept of a national information system.

The first step, I see, is a very thorough and comprehensive feasibility study of the entire issue. It would probably cost in the range of two to three million dollars to make the study. The goals should be to examine every aspect of both design and operation of the system. The study must define the system objectives, define the data requirements and standard codes to be used, explore various alternative system approaches, perform an in-depth cost benefit analysis, develop manpower projections, perform equipment evaluation, assess the training and education needs, and so forth.

No doubt at this time, we are talking about a vast computer data communication system. Some people envision computer terminals in every pharmacy. I would say that depending on the type and location of the pharmacy and the volume per day of third party claims, that different levels of pharmacies would require different kinds of terminals, even to the point that many thousands of pharmacies would not justify a terminal set-up and would continue to use contemporary manual means of forwarding prescription record information. It is estimated that approximately 25,000 pharmacies dispense 70-75% of all prescriptions. These pharmacies constitute the hard core for a drug information network.

Design Phase Problems

In the systems design phase, the primary functions are the development of the computer programs, which we call software, and the selection, placement, checkout, and implementation of the computer equipment which we call hardware. One basic question that would have to be addressed immediately would be whether or not the system needs to be operated on a real-time on-line basis or could be satisfied with a batch inbound transmission system. That is, as the patient presents a script to the pharmacist and the pharmacist enters the information into the terminal, on site at his location, would the information have to be immediately transmitted or relayed to the regional computer center while the patient is still in the presence of the pharmacist? Or could the information stay within the terminal at the pharmacy and be transmitted to its associated computer during unproductive hours, or, perhaps at night. The difference in cost is quite significant between these two different modes of operation. For instance, costs are tremendously increased if the more immediate communication system were adopted in terms of (1) telephone communication costs, by a factor of five or more, (2) the capabilities and optional features required of the pharmacy terminal equipment, especially if the system requires a two-way communication link between the pharmacy and the computer, (3) the size and sophistication of the communications control equipment located at the regional data center, (4) the file storage requirements at the regional data center, and the size of the computer itself, (6) the scope and complexity of the programming requirements for the operating system. All these factors increase in complexity, size, and cost significantly if one were to adopt an online communication system.

Other major problem areas would be in providing the appropriate manpower resources for the design and development of the system. Specialists would have to be recruited in the areas of systems analysis, and program specifications, data control functions, applications programming, telecommunications analysis and programming, and technical writing. Also the training and education of the pharmacists and his assistants would be a gigantic task. This effort would start in the design phases, and be a continuing effort during system operations.

Another problem is the study and definition of standard in-bound and out-bound data transmission requirements. These would have to be uniformly applied to all pharmacies using the network and to all other users such as drug insurance carriers, wholesalers, manufacturers, etc. Universal coding requirements or identification schemes must be developed, maintained, and utilized for the effective operation of the system. Such things as the physician identification number, the pharmacy identification number, the drug item identification number, including dosage form and strength, the dosing instructions to the patient, the days of supply would have to be standardized and used throughout the country for the national system. I realize that major efforts have already taken place, such as the development of the NDC Code for drug identification and the NPIC code for pharmacy identification. All the data fields in a prescription record which can be subject to a standard national coding scheme would have to be developed and disseminated to users during the design phases of the system.

Need for a Pilot Program

The most logical approach in the design and implementation of the system would be to pilot test any developed operating system in a real life environment. During the pilot study the programs, equipment, and interfacing with the pharmacist and other users could be tested and various corrections could be made in the operating procedures. Specific weak areas in training manuals and training seminars could be ascertained and corrected and all other aspects of the system could be evaluated before a commitment is made for the expansion of the system to a national level. The pilot area could also serve as a continuous test area in the development of new applications and validation of new programming packages. In other words, the communication network for processing third party payment prescription claims could be tested in a pilot area and if successfully proven, this application could be scheduled for expansion into other areas across the country. While this expansion for the claims processing function is taking place, other applications could be developed and tested in the pilot area, such as the communication system for transmitting prescription credit sales data to credit institutions and banks. Or the inventory data system which would transmit prescription usage data to pharmacy-selected wholesalers and manufacturers.

Cost Estimates

Initially, the first such major system to be tested in the pilot area, and let's assume at this point it is drug insurance claim processing, could cost as much as five million dollars, again depending on which approach is adopted. Additional design and development money would have to be poured into the pilot area as new applications are developed and new software approaches and equipment evaluation is assessed. Without having the opportunity to study all the cost factors associated for a comprehensive design phase of this system, I would say that a total price tag of 25 million dollars or more would be required for the relatively less sophisticated system and 100 million dollars and more for the on-line system to set up the system on a national level for the initial application areas we discussed. Once the system is functional, there are numerous operational problems to be considered.

Let's look at operating costs. Computer terminal equipment at the retail outlet level could cost from 25 to 40 million dollars a year. Regional data center computers which would have the capability of receiving prescription record information from the pharmacy and responding proper information back to them and also having the message switching capability necessary to transmit the appropriate information to the designated drug insurance carriers, banking or other credit institutions, and various drug distribution levels, could cost upwards to 60 million dollars annually. All the regional data centers would need reliable failsafe and backup equipment to provide for the system operation during periods of system failure and maintenance.
Users of the system, such as manufacturers, wholesalers, drug insurance carriers, would no doubt have to enhance the capability of their own computer sites to accommodate the communication system. This alone, on a national level, could cost 10 million dollars or more annually for the data control equipment. Also conceivably, an extremely large sophisticated computer would be linked to all the regional data centers for the collection of drug utilization statistics. Such a computer could be used to compile a huge data bank of drug utilization which could service utilization studies and provide statistical information to all users within the system. Patient drug history information could be maintained at the regional data centers but an interaction between all data centers in the country would have to be established to accommodate patients when they move from one regional area to another.

The maintenance and servicing of such a system is also a significant factor. A sizeable staff of systems analysts and systems engineers would have to be retained to maintain the system operation and also to incorporate new programming applications or features required in the system. Also modifications to the system that would take place would have to be installed on a uniform basis at every regional data center used throughout the country. Cost for such a staff and travel time involved could run from 10 million dollars and above. Additional staff members would have to be recruited to conduct training courses and seminars for pharmacists and users of the system. Communication cost we touched on, and this is quite significant in any computerized drug information system. Again, a real-time, on-line system might cost as much as five times the communication charges for any batch data transmission system. In other words, if the communication costs associated with the batch operation would cost 5 million dollars, approximately 25 million dollars would be required for the on-line system. I have no doubts in my mind that an information system of this size and proportion dealing primarily with the communication functions we discussed would cost not less than 150 million dollars annually for on-line system and 40-50 million dollars for batch system. This does not include any modification or operating costs that would be borne by the users for their own application. A sophisticated accountability system would also have to be developed to insure that all users are paying a prorated share of the operating costs.

Timing Plus Other Problems

Let me conclude my remarks by saying that:

(1) there is no doubt in my mind that there is a need for a national drug information system in light of the changing environment of drug distribution methods, reimbursement methods to the providers of service, and the public health needs of the country,

(2) if we are going to start to do anything in this area, it must be done now because, in my opinion, time is working against us. As more and more money is poured into systems design and development of operating systems for the various applications we discussed on a decentralized and non-uniform basis, the more resistance and reluctance there will be to change and modify existing operations,

(3) any pilot studies which are now being conducted which can lay the framework of the data requirements or specifications for a national drug information system whether it is being funded from public or private sources must be expanded,

(4) the successful implementation and operation of the system of this nature requires a national commitment from all parties involved and associated in the drug delivery field. I do not see any other way that such an undertaking of this size stands any chance of success without the fullest cooperation and coordination between all parties involved.

I firmly believe that a national commitment would be, to say the least, an extremely difficult and probably impossible goal to achieve without a leadership role coming from the Federal government. For this scheme to have any chance of success, I am firmly convinced that HEW must assume a positive active role in acting as the catalytic agent in bringing together the various parties involved in the drug delivery system. I am also firmly convinced that to provide the cost justification impetus for the development of such a system, a Medicare out-of-hospital prescription program must be adopted and instituted.

I believe that HEW must take several steps to start the movement of an information system in this country.

(1) All possible users of the system should be invited to participate in sessions to prepare specifications and requirements for the system. The users themselves could be assigned into their respective functional areas, and they could develop those aspects or requirements of the system pertaining to their applications. Joint sessions could then be held to coordinate the overall data requirements and systems objectives for the system for all possible users.

(2) If step one were successful, I believe that the government and private industry should fund a comprehensive and in-depth feasibility study to assess the value, contributions, and cost benefit analysis for the design and implementation of such a system. Such a study should not only answer the economic justification for such a system, but should also outline those areas for future study and possible approaches for them.

(3) If justified on a functional basis, each major organization could then sponsor independently-conducted systems studies to determine the best hardware/software design configuration necessary to produce the objectives called for. Upon the completion of these studies the representative group that established the objectives could be reconvened to evaluate the findings. If the resulting composite system design appears feasible, cost effective, and capable of meeting objectives, each potential user would be asked to sign a contract to cooperate in the creation and operation of the terminal computer communication system.

To summarize, we have just begun to scratch the surface. A little has been done, but a tremendous task awaits us that must begin now if we are to have the kind of a system needed in the drug information area.

PRACTICAL APPLICATIONS OF INFORMATION SYSTEMS

John T. Fay, Jr.
Vice President, Professional Relations
McKesson & Robbins Drug Company

This week in the book review section of the Sunday New York Times, critic John Leonard has some very perceptive comments that seem to me to relate to our general objective here. Mr. Leonard says "... things being what they are, which is not what most of us would wish them to be, one can't walk down the streets of the mind these days without getting mugged by a single cause. The single cause usually has an accomplice also, the single cure." To make his point, he includes among the single causes - original sin, sexism, the economic system, the death of God, and Mayor Lindsay. Among the associated single cures he lists - Sesame Street, R. D. Laing, water beds, tactical nuclear weapons, and Jane Fonda. Illustrating the current argument between science and the humanities he concludes at one point with this comment about humanists. "When the going gets tough, the humanist gets subjective; don't tell me that there aren't any shadows on the wall of the cave; science has created a world in which men do things not because they want to, but simply because they know how."

My own question to you is....in the present state of the relationship between computerization and the practice of pharmacy, have we in fact created something here that we really don't want to do, but we're about to do because we think we know how? I hope not. Certainly, all of us meet representatives of the disaster lobby who are convinced that Chicken Little was right - the sky is falling. Not so, in my opinion. There is plenty of room for optimism. It appears to me that many of the systems now in use are leading us along the right track toward more intelligent application of computer technology in professional practice.

Today I want to review briefly with you six applications of computer technology now in use by McKesson & Robbins Drug Company and its associates. These six are: DRS, Comp-U-Serv, EPIC, RIC, Economost, and PCS. Surely, none of them provides a single cure for the myriad problems that face us, but elements of each of them are leading us toward an integrated overall system that does hold great promise. As you know, McKesson & Robbins Drug Company is the largest and the only national drug wholesaler in the United States. We do something in excess of $700,000,000 a year in wholesale drugs at about 90 locations. Some 14 or 15 years ago, the drug company began considering how to use the computer. The first installation was in Detroit, using a system now considered ancient - Univac. Today our organization has five data processing centers planned to service our own needs, with four of these fully operative in New Haven, Detroit, Memphis, and Dallas. Better than 60% of our own inventory is now computerized and we expect that the process will be completed sometime next year or early 1973. With computerized inventory management and accounting we have improved our service level to our own community pharmacy customers by as much as 20%. When our inventory management program is on line in a given market, there are a number of other ways that we can utilize the equipment because of its memory and calculating capacity. As Mr. Danziger and others have pointed out, computers cannot think. However, they remember a hell of a lot.

Accounting Assistance

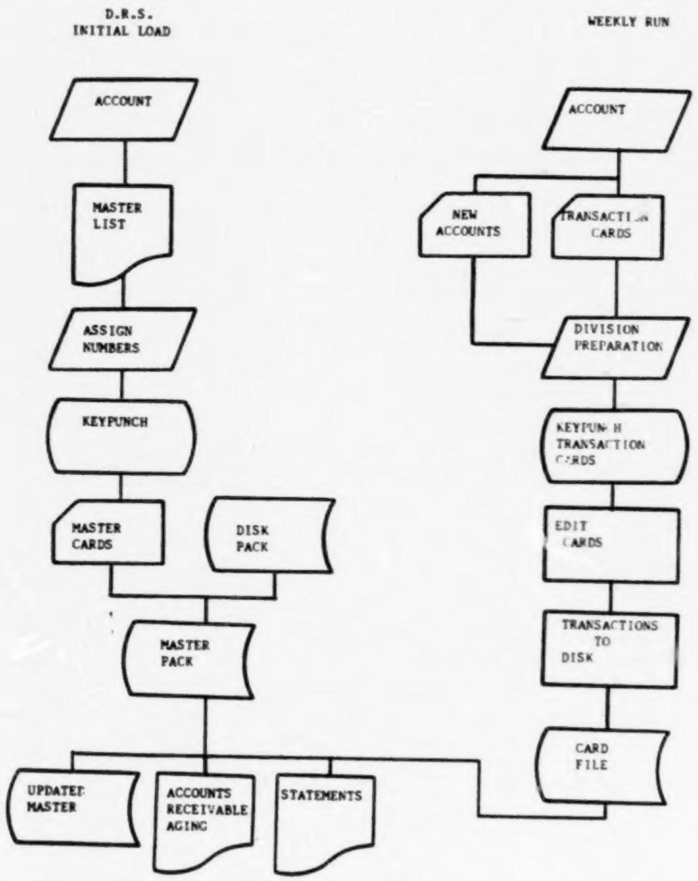
DRS, originally called Drug Record Service, is a computer service that provides the pharmacist's customers with a professionally prepared monthly statement of cash and credit purchases. DRS offers a scientific approach to the management of accounts receivable using electronic data processing. There are a number of other such systems in use in the country but we think that DRS has many significant features that provide a more comprehensive service. Other wholesalers, local banks, and service bureaus are competing with us in this field. The slides illustrate some of the particular features of DRS and included also are flow charts that trace the production of DRS through the computer (DRS 1 + 2). The customer's statement contains a monthly and year-to-date record of those transactions which may qualify as medical deductions on Federal income tax or which may be reimbursable expenses under various health insurance programs.

With this system, the pharmacist can exercise better control over credits and receivables. Like inventory management, receivables must be viewed in terms of the investment carried. Part of this system is a very useful management tool that we call an Aged Trial Balance. This summary alerts the pharmacists to problem areas in customer buying patterns and gives him a chance to recapture business that may be lost. Specifically, DRS offers increased business because of greater consumer traffic and greater pharmacy loyalty, which means more sales and more profits. The pharmacist can achieve reduction of bad debt losses using the Aged Trial Balance and eliminate many hours of manual bookkeeping.

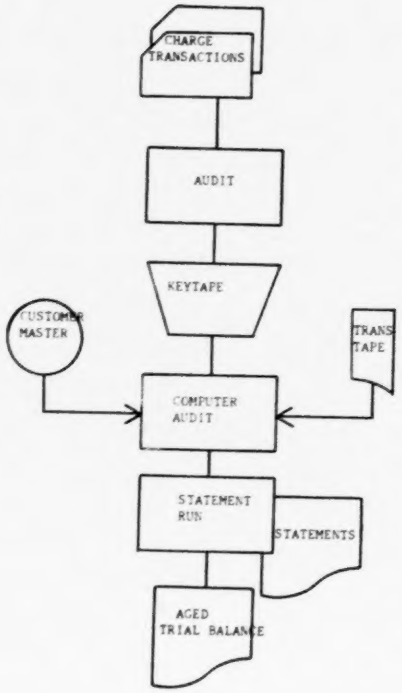
The second generation of DRS is a plan we call Comp-U-Serv, essentially a computerized service for handling accounts payable and general ledger. (See flow chart.) For accounts payable, Comp-U-Serv provides checks, prepared and mailed to all of the pharmacy's suppliers; discounts calculated automatically; computerized monthly records for bank reconciliation; and, versatility - stop-payments on checks can be made when the check has not already cleared the bank. The manager makes out only one check for each group of invoices submitted and receives a complete record of every transaction plus a list of checks outstanding every month.

Additionally, Comp-U-Serv provides a mid-month balance summary for better control of cash. For general ledger handling, Comp-U-Serv offers a complete financial presentation of business in an easily read format. A comparative analysis by month and year-to-date is shown and the system produces a year-end ledger. We can give a departmental analysis of sales and costs for as many as five departments. Comp-U-Serv is available in several markets now and is offered by McKesson Divisions that have a 360-20 disc system. Surely, you can see how this relates to another problem area - the matter of selling price determination and price changes. In the immediate future, we will expand Comp-U-Serv to include payroll

DRUG RECORD SYSTEMS

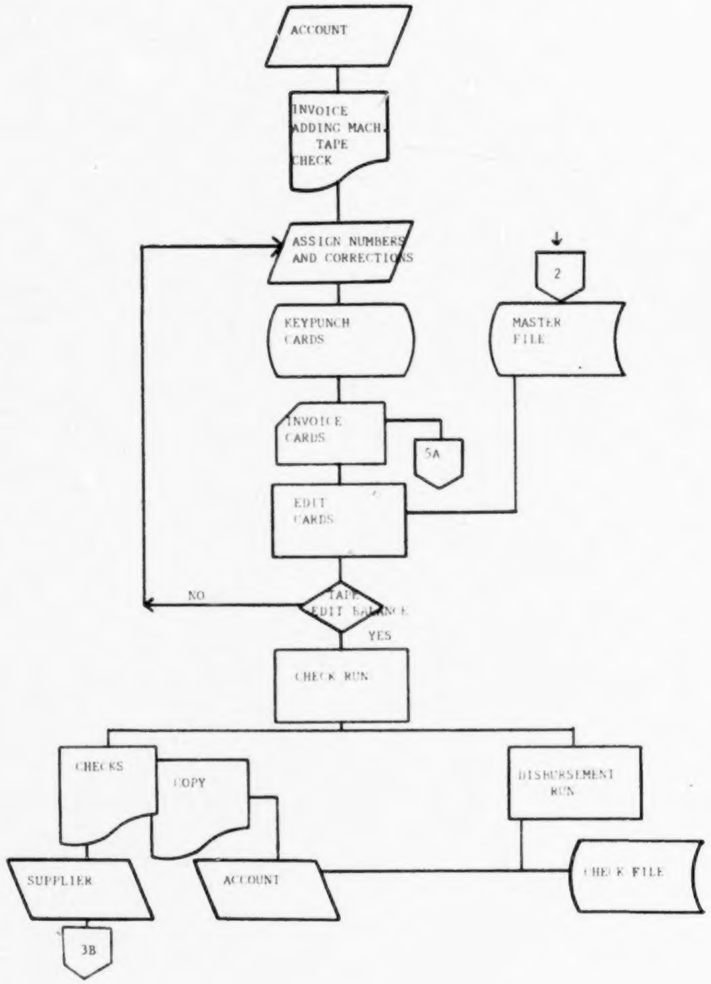

D.R.S.
INITIAL LOAD
ACCOUNT
MASTER LIST
ASSIGN NUMBERS
KEYPUNCH
MASTER CARDS
DISK PACK
MASTER PACK
UPDATED MASTER
ACCOUNTS RECEIVABLE AGING
STATEMENTS
WEEKLY RUN
ACCOUNT
NEW ACCOUNTS
TRANSACTION CARDS
DIVISION PREPARATION
KEYPUNCH TRANSACTION CARDS
EDIT CARDS
TRANSACTIONS TO DISK
CARD FILE

DRS 1

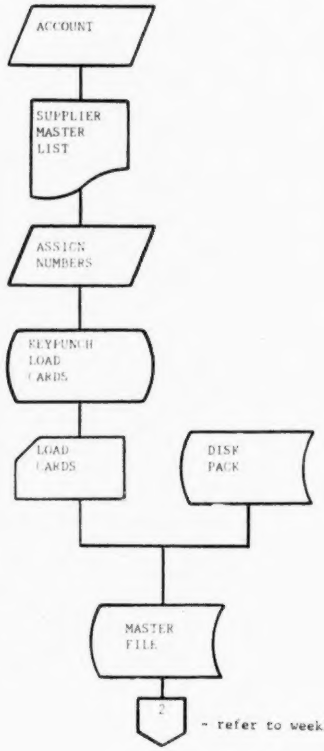

CHARGE TRANSACTIONS
AUDIT
KEYTAPE
CUSTOMER MASTER
TRANS TAPE
COMPUTER AUDIT
STATEMENT RUN
STATEMENTS
AGED TRIAL BALANCE

DRS 2

COMP-U-SERV
WEEKLY RUN


ACCOUNT
INVOICE ADDING MACH. TAPE CHECK
ASSIGN NUMBERS AND CORRECTIONS
2
MASTER FILE
KEYPUNCH CARDS
INVOICE CARDS
5A
EDIT CARDS
NO
TAPE EDIT BALANCE
YES
CHECK RUN
CHECKS
COPY
DISBURSEMENT RUN
SUPPLIER
ACCOUNT
CHECK FILE
3B

COMP-U-SERV
INITIAL LOAD


ACCOUNT
SUPPLIER MASTER LIST
ASSIGN NUMBERS
KEYPUNCH LOAD CARDS
LOAD CARDS
DISK PACK
MASTER FILE
2

- refer to weekly

and tax computations. The computer programs to accomplish this are being written now. Eventually, the wholesaler's computer can completely remove the pharmacist's current obligation as a part-time accountant.

The third program illustrated in this review is an in-house procedure that we call EPIC. It was devised to provide our customers with an invoice that was far more comprehensive than the invoice then in use. In addition to basic pricing information, the pharmacist is advised of price increases, decoding of drug abuse items, retail prices, and discounts. Although EPIC was developed as an entry program for invoicing our customers, it became a natural factor for associated inventory control. Presently, more than thirty of our divisions are now linked to home office computer billing using the 360-30 system. From this activity we expect to develop procedures that can be useful in the prevention of adverse reactions. As you know, there are many different types of family prescription record systems now in use and almost all of these are maintained by hand. Very soon we anticipate a computerized system that will accommodate the needs of accurate record keeping in order to avoid adverse reactions. As has already been mentioned here, the problem is increasing in severity as more individuals see several prescribing physicians.

Inventory Control Applications

The EPIC system led quite naturally to the fourth program I listed earlier called RIC, an acronym for Retail Inventory Control. RIC has been developing for sometime in one test area. The system depends, in part, upon a computer produced press-apply label. Each product shipped to the pharmacy has one of these labels attached to it. At the time of the sales transaction, the sales person removes the press-apply label and places it in a book. The book subsequently is collected by a McKesson representative or sent to a computer center. One of the difficulties with the system is the sales person forgetting to remove the label at the time of the transaction. But it is possible to build check points into the system that accommodate even this difficulty. As the flow charts show, the RIC system repeatedly accomplishes a statistical analysis leading toward the intelligent management of EOQ established item minimums - Economic Order Quantities. Many of the elements shown in the flow charts for the RIC process have led to additional improvements in the programs now under development.

Automated inventory control and improved operating efficiency are laudable goals. Many wholesalers with computer capacity now have a variety of approaches to this problem. Perhaps you have read about the North Western Velocity program and about MINT. The most sophisticated approach that we have yet developed is operative in San Francisco - the Economost program. Economost illustrates one general approach to the marriage between the retailer and the wholesaler with the computer acting as the marriage broker. It is a totally integrated distribution system. Currently, there are more than forty affiliated pharmacies on line in the system. A plan-o-gram is developed for each department in an Economost pharmacy, to make the best use of available shelf space for some 6300 items that account for about 90% of the business in a typical pharmacy. The warehouse is fully computerized and linked directly to the associated pharmacy by telephone transmission of reorder data, collected weekly with an electronic console that is wheeled through the pharmacy. After data collection in the pharmacy's console, the order is placed over the telephone line at the rate of 130 invoice lines per minute. An important feature of the program is the once-a-week delivery schedule and the fully cooperative effort between retailer and wholesaler to manage inventories most effectively.

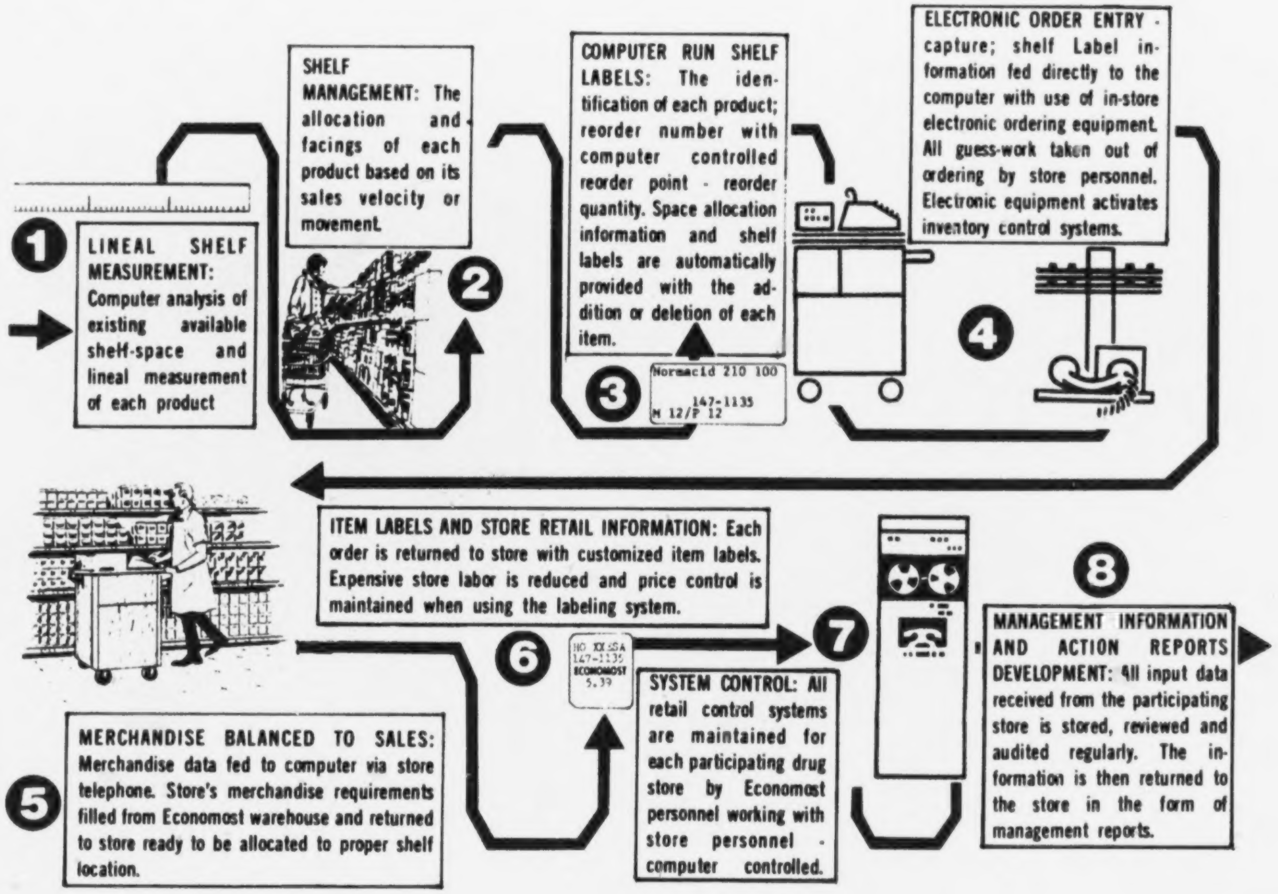
Economost is one of the most elaborate approaches to computerized inventory control that we have - but, to cite the Chinese philosophers - "a journey of a thousand miles begins with just one step." Again, the first step that we suggest is DRS. Please bear in mind that we are not naive enough to think that any one of these programs offers the single cure. Neither do I look for some computer programmer to come staggering out of the laboratory, draped with wires and with tears in his eyes, sobbing "...My God, I found it." This is just not likely to happen, especially if you know many computer programmers. However, all of the programs that we are discussing today do work. Some of them squeak a little bit, but they do work. The Economost program is not for the small pharmacy that finds itself in trouble. It has been developed for the relatively successful large merchandising pharmacy with a need for greater growth. As shown in the charts, the systems available in Economost include: Scientific shelf management and a product allocation system, an inventory control system based upon electronic order entry and data capture and a management information and reports system. These systems have been tested and proven. Economost associates have obtained increased asset management capability and increased profitability.

Third Party Payments

The last series of illustrations describe PCS - Pharmaceutical Card System - a McKesson subsidiary. With two years of operating experience now, PCS has demonstrated that third party payment plans can be feasible, practical and easy to use for plan underwriters, community pharmacies, and beneficiaries. PCS serves as a nation-wide clearinghouse for prescription benefit claims, making consolidated payments to pharmacists twice a month and consolidated billings to underwriters. We are especially proud of the fact that PCS has never missed a payment schedule to participating pharmacists. Without exception, PCS member pharmacies have been paid on time every two weeks. Currently, PCS serves twelve major insurance companies with thirty-nine different plans. The growth of this organization has been somewhat slowed by the recession and the failure of some employers to add this benefit as had been originally planned.

PCS uses a plastic card to identify each of the beneficiaries under third party payment plans. The card provides a basis for semi-automated input of beneficiary information and eligibility checks. With his payment every fifteen days, the pharmacist receives a complete summary statement of all of the transactions administered by PCS. Similarly, the insurance companies acting as payers receive complete summary statements of all the transactions in each of the plans they underwrite. The system offers a clearinghouse procedure much like the Federal Reserve System for bank checks. The economy, quite naturally, comes from channeling the paper through one source - an analogous situation to the function performed by drug wholesalers. More than 7,000 pharmacies are now active in the system and enjoying the many benefits that PCS provides. The flow chart indicates the computer process used at the Phoenix Data Center by PCS. The equipment there is a GE-415 computer with Honeywell key tape input.

OPERATING CYCLE FOR ECONOMOST CONTROL SYSTEM



1 **LINEAL SHELF MEASUREMENT:** Computer analysis of existing available shelf-space and lineal measurement of each product

2 **SHELF MANAGEMENT:** The allocation and facings of each product based on its sales velocity or movement.

3 **COMPUTER RUN SHELF LABELS:** The identification of each product; reorder number with computer controlled reorder point - reorder quantity. Space allocation information and shelf labels are automatically provided with the addition or deletion of each item.

4 **ELECTRONIC ORDER ENTRY** - capture; shelf Label information fed directly to the computer with use of in-store electronic ordering equipment. All guess-work taken out of ordering by store personnel. Electronic equipment activates inventory control systems.

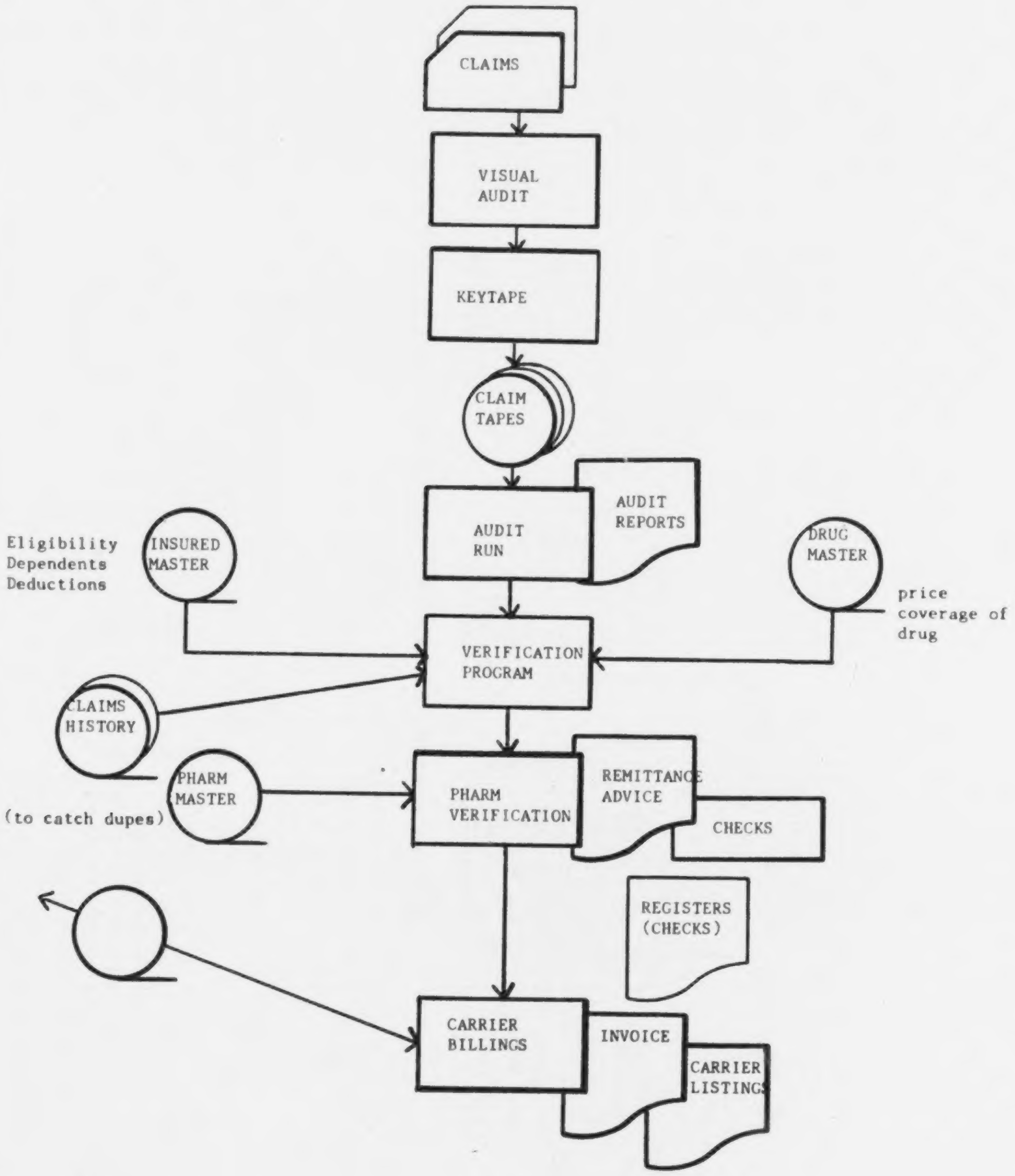
5 **MERCHANDISE BALANCED TO SALES:** Merchandise data fed to computer via store telephone. Store's merchandise requirements filled from Economost warehouse and returned to store ready to be allocated to proper shelf location.

6 **ITEM LABELS AND STORE RETAIL INFORMATION:** Each order is returned to store with customized item labels. Expensive store labor is reduced and price control is maintained when using the labeling system.

7 **SYSTEM CONTROL:** All retail control systems are maintained for each participating drug store by Economost personnel working with store personnel - computer controlled.

8 **MANAGEMENT INFORMATION AND ACTION REPORTS DEVELOPMENT:** All input data received from the participating store is stored, reviewed and audited regularly. The information is then returned to the store in the form of management reports.

PCS - CLAIMS PROCESSING PROCEDURE


CLAIMS
VISUAL AUDIT
KEYTAPE
CLAIM TAPES
AUDIT RUN
AUDIT REPORTS
Eligibility
Dependents
Deductions
INSURED MASTER
DRUG MASTER
price
coverage of
drug
VERIFICATION PROGRAM
CLAIMS HISTORY
PHARM MASTER
(to catch dupes)
PHARM VERIFICATION
REMITTANCE ADVICE
CHECKS
REGISTERS (CHECKS)
CARRIER BILLINGS
INVOICE
CARRIER LISTINGS

Our experience with PCS led naturally to the introduction of Complimentary Prescription Service, a joint venture with R. A. Gosselin & Company. Complimentary Prescription Service now has five major pharmaceutical manufacturers as clients and is growing rapidly. Using this service, the manufacturer provides pre-printed prescription blanks for distribution in place of physical samples. In effect, the patient receives a starter dose without charge using traditional methods. The blank also provides an option by physician authorization for refills at the patient's expense. Existing inventory is used, a fact that also benefits the wholesaler, and the pharmacist receives reimbursement through the Pharmaceutical Card System payment mechanism. The CPS plan is operative now and will be a source of new pharmacy volume.

Finally, I am convinced that profit making private industry can be used effectively in the public interest. And I believe that Dr. Alton Doody is right when he says that inevitably there will be a vertically integrated programmed relationship between drug wholesalers and retailers. To accomplish many of the steps already taken that lead towards national health insurance, we will eventually need a massive computer network that will record prescription data and other information elements linking every pharmacy and physician's office in the United States. There is no need for a system of Government-operated separate computer centers to accomplish this task. We have the capability now, and we have the interest to pursue refinements of the necessary programs. New technology that will eliminate the need for paper forms and provide direct data transmission is now available. Later this year we expect to announce a test of a very sophisticated data transmission device that can be leased at a relatively low cost.

Certainly, there is much here to worry about and I remind you that there are those who say that worry kills more people than work. But it could be that the reason worry kills more people than work is that more people are worrying instead of working. Let's get to work.

A MODEL DRUG INFORMATION SYSTEM

William J. Wollenberg, Dr. Eng.
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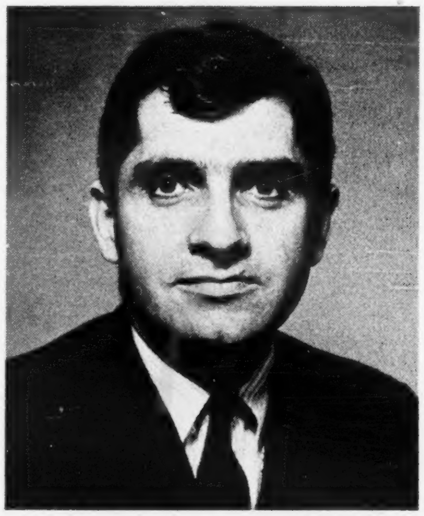

The prescription pharmacy is not an independent enterprise. It is basically a supporting service that depends mostly upon the larger medical system surrounding it for its activity. Furthermore, this medical system is only one part of a much larger health care system that serves a population area. This health care system is comprised of activities such as medical, dental, mental health, nutrition, and social services. All of these services interact, either directly or indirectly with the pharmacy. All of these services in some way shape the activities of the pharmacy. An understanding of the future role and structure of the pharmacy demands that we develop a good perspective of this health care system a few years hence. This paper begins with a brief generalized discussion of research and developmental activity in automated health care systems, then reviews a few major automation projects. The discussion finishes with a proposed approach to a community-based automated system.

Background

The technology of data collection and processing has been revolutionized in the past ten years by the digital computer. Cost reductions resulting from replacing personnel in labor-intense functional areas has been well documented and they are especially cogent to many medical system analysts and administrators who were struggling with the problem of controlling medical care costs, particularly hospital costs. In the past several years, many projects have been undertaken for the purpose of demonstrating that the automation of medical services will reduce the cost and/or improve the effectiveness of health care. To date, these projects have provided little visibility into how to achieve these objectives.

Analysts, administrators, and physicians were aware of the fact that physicians and nurses were spending a great amount of their time performing tasks that represented poor utilization of their training and capabilities. Accumulating and updating patients' records is one example. It was believed that the computer could absorb these chores, thereby providing these professionals more time to spend on diagnosis, decision-making and direct patient care. The prognosis was a more cost-effective patient care system.

However, few of the characteristics necessary for successful application of a computer were present. Favorable cost/benefit applications usually consist of well-structured techniques used in routine and repetitive operations. Medical care is essentially an unstructured area. There are no standard techniques for acquiring, organizing, using, and analyzing medical data in a scientific manner. There are a few lines from Through the Looking Glass, by Lewis Carroll, that seem appropriate here:

> "When I use a word" Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean - neither more nor less." "The question is," said Alice, "whether you CAN make words mean so many different things".

Several physicians can interview a patient, and each will use his own format and produce a different medical history -- and possibly a different current diagnosis. In addition, diseases and conditions do not manifest themselves in routine patterns that readily lend themselves to diagnostic algorithms. The result has been considerable disappointment for those seeking cost reductions. Even those expecting to improve effectiveness have not come close to realizing their goals.

When the technocracy turned to this problem, it went either of two ways. The more research inclined practitioners of computer science sought the satisfaction of the sophisticated analytic problems, such as diagnosis. Others merely tried to adapt the computer to the existing methods for doing a job rather than identifying the needs and designing a new system that best met those needs. Both efforts have failed mainly because they did not recognize that the structured information base so necessary to a science does not yet exist in medicine. It was like trying to solve an arithmetic problem without having a numbering system available.

Status of Patient Care Systems

A 1968 survey of hospitals throughout the country conducted for the Department of Health, Education and Welfare indicated that only 1.3 percent of the computers were installed for purposes of hospital information systems, although about 16 percent were using them for such purposes.[1] This use, however, was mostly applied to medical record file maintenance, indexing and statistics. There was no indication of an automated structured information system containing drug information, treatment plans, and medical records. Furthermore, the study indicated that documentary evidence of actual savings was lacking. Similarly absent was "accurate information regarding costs and disadvantages of computer systems. Too much of the information disseminated is theoretical and has not been tested and debugged in actual situations for a community hospital (as distinguished from a well endowed research associated hospital well supplied with public grant monies)."

The situation has changed somewhat since 1968. Today, much of the computer-oriented developmental work is in the areas of past histories and clinical operations. Let us examine a few of these projects.

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[1] U. S. Department of Health, Education and Welfare, Public Service, "The Use of Computers in Hospitals," prepared under Contract Number PH-110-233.

Patient History

The term patient history refers to the visible product of aggregating and updating the patient's record. Demographic, dental, medical, etc. profiles are included in the data. Most of the automation work has concentrated on input rather than on output, i.e. on data collection rather than on organizing data for the user. Since 1966, at least a dozen automated medical history projects have been carried on at medical schools, clinics, institutions, hospitals and in private companies from San Francisco to Boston.[1] Essentially, each of these projects involved an interface between the patient and an electro-mechanical device that asked questions and took replies. This device was either a teleprinter or a teleprinter/video display combination tied into a computer.[2] Generally, the patient uses the device in a conversational mode, i.e., questions are typed out or video displayed and the

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[1] For example see the following:

a. W. V. Slack, G. P. Hicks, C. E. Reed, and L. J. Van Cura, "A Computer-Based Medical History System," New England Journal of Medicine (January 27, 1966), pp. 194-198.

b. J. C. Mayne, W. Weksel, P. N. Schultz, "Toward Automating the Medical Record," Mayo Clinic Proceedings, 43, 1 (January 1968).

c. R. Stilman, W. T. Ruth, K. M. Colby, and C. P. Rosenbaum, "An Online Computer System for Initial Psychiatric Inventory," American Journal of Psychiatry, 125, 7 (January 1969 supplement).

d. J. Grossman, G. O. Barnett, and D. Swedlow, "The Collection of Medical History Data Using a Real-Time Computer System," Proc. Conf. on Engineering in Medicine and Biology, 10, 39.1 (1968).

e. "Applying Computer Procedures to Hospital Psychiatry," Frontiers of Hospital Psychiatry, Roche Report, 3, 19 (October 1 and 15, 1966).

f. B. C. Gluck, Jr. and C. F. Struebel, "The Computer and the Clinical Decision Process," American Journal of Psychiatry, 125, 7 (January 1969 supplement).

g. Morris F. Collen, "Periodic Health Examination Using an Automated Multitest Laboratory," Journal of the American Medical Association, 195 (March 7, 1966); testimony, Dr. Morris Collen, Hearings Before the Subcommittee on Health of the Elderly, 89th Congress, Second Session, September 20 to 22, 1966; "Computers in Multiphasic Screening," Computers in Biomedical Research, Chapter 14, Vol. 1 (Academic Press, New York and London, 1965).

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[2] Some systems are connected in real time to a computer, but variations include projector displays, simple local logic, and tape cassettes.

patient selects from a multiple choice answer set. The answer is selected by pressing a key on the keyboard or by touching the video screen with a light pen. The computer chooses the next question based upon the answer given. The number of questions asked and the length of the interview are a function of the amount of logic programmed into the computer and the efficiency of eliminating irrelevant questions. Typically, an efficient program might ask only 150 questions from a total library of 700 questions.

Clinical Care

The other major category of computer applications has been in clinical operations. These include patient monitoring, scheduling, tabulation of treatments, tasking of laboratories, reporting test results and prescriptions ordering. Clinical automation has focused mainly on hospital settings. These systems perform a large number of functions and tend to be sophisticated, complex and costly. There are more than a half dozen of these projects being carried on by industry and institutions. I will quickly review only three that I believe to be the most operational.

Texas Institute for Rehabilitation and Research (TIRR), a 56 bed intensive-extended care facility has the most operational system in place.[1] Input/output terminals are located at several strategic stations throughout the facility and consist of teleprinter and video displays. The system was developed by the institute staff and has been operating since 1968. It performs seven major functions: Admissions-Discharge, Scheduling, Pulmonary Function Reports, Laboratory Test Results, Bedside Data, Disability Profiles and Urology Data.

The TIRR system is interesting, not only because it is essentially fully operational, but also because it has been fully integrated into the daily routine of the staff and has their acceptance. Furthermore, the system has operated long enough for it to be possible to analyze its operational impact. In house studies (which probably need refinement) indicate about a 25% reduction in stay time for patients. This, in part, is attributed to the patient daily activity schedule prepared by the system. To the staff, the schedule represents daily achievement goals. As a result, patients get to the proper therapy stations on time, spend the full amount of time in therapy and generally make more effective use of their time. The cost of this system averages out to about $10 per bed per day. If this computer system does yield a 25% reduction in stay time, then it becomes cost-effective at a facility with an average bed-day cost of more than $40. It is not obvious that the system can provide this result in non-similar settings.

The second system of interest, called REACH, was developed using private resources. REACH is a comprehensive computer communication system encompassing almost every hospital activity including patient care, fiscal services and statistical analysis.[2] This system was essentially fully developed at the company prior to installation at a hospital and, in many ways, is an admirable example of engineering. Although human engineering played a role in the REACH system development, the hospital staff that was to use it played no role in its day to day development. As a result, there was little staff identification with the system when it was installed at the Baptist Hospital in Beaumont, Texas. In fact, the staff, particularly the physicians, refused to use the system. The system is still not operational some two years after installation. Costs are about $10 to $14 per bed day, or about $750,000 per year for a 200 bed hospital. This system is also being installed at another hospital in Florida. Since neither installation is operational, no impact data are available.

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[1] Gotcher, S. B. et al, Daily Treatment Planning with an On-Line Shared Computer System, Methods of Information in Medicine, Vol. 8, No. 4 (October 1969) pp. 200-205.

[2] Patient care includes: morning report, bed census, test and treatment schedules, updating the record, etc.; fiscal service includes accounting, payroll, purchasing, and statistical analysis includes utilization reports.

The third system (Technicon Medical Information System) was also developed by a private organization, but in close cooperation with El Camino Hospital staff at Montvale, California. This system also encompasses almost every hospital function. The system is not yet fully operational, but was recently chosen by the National Center for Health Service Research and Development as a recipient of additional funds with the intent of evolving it as a prototype system. Operating costs appear to be in the neighborhood of $10 per bed day.

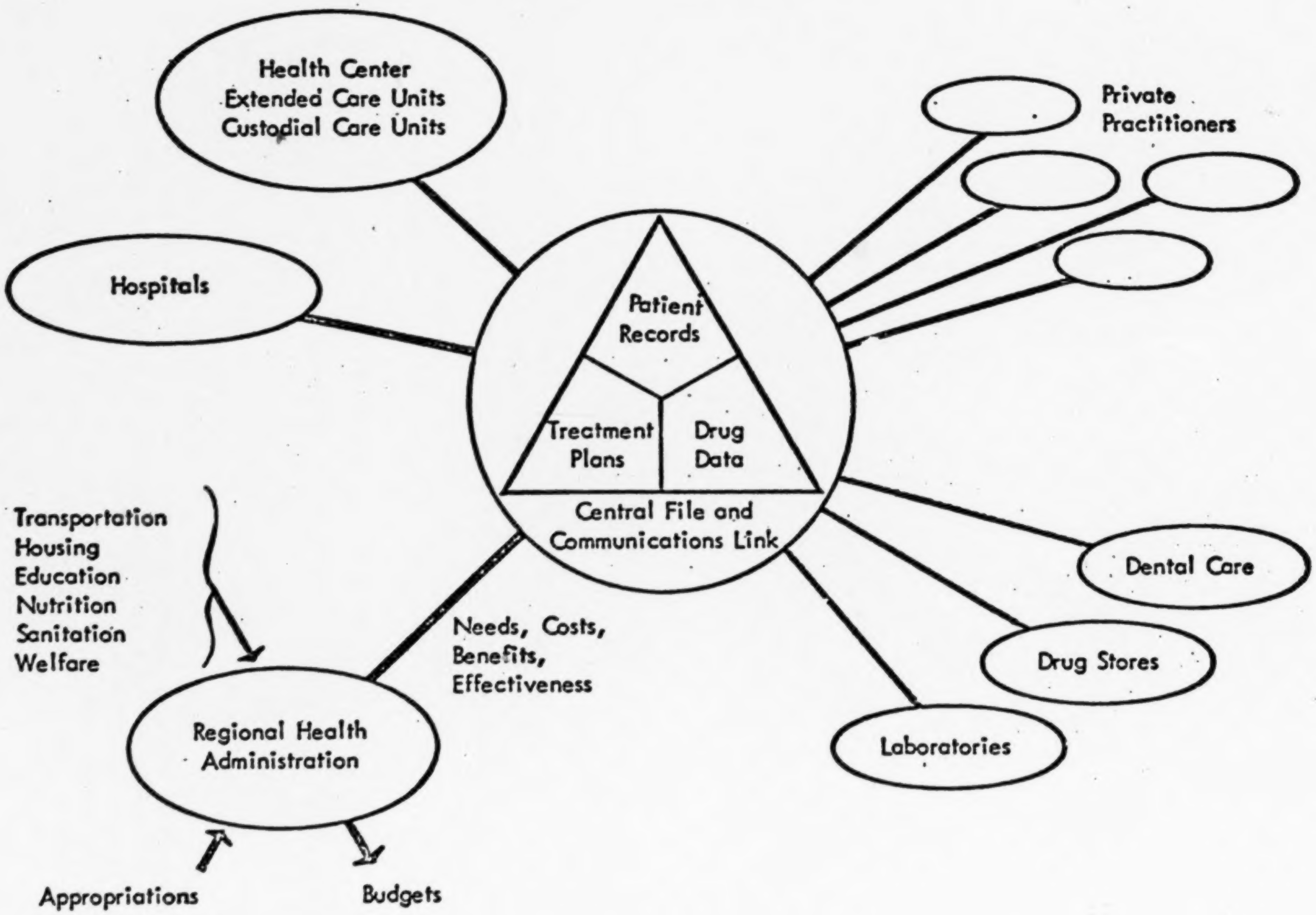
The general lack of success to date in controlling costs and improving effectiveness is due mainly to a lack of understanding of the real problems. More specifically, the major shortcomings common to all these programs are that:

- They did not take a systems approach to health care as a problem of patient-health management involving many services and many professional personnel.
- In limiting their focus on the hospital, they failed to understand the problem. They dealt more with a manifestation of the health care problem, than the problem itself.
- They adapted computers to existing techniques and operations rather than develop new approaches using cost/benefit analysis.

Schematic of a Total System

A systematic analysis of the problem might well begin by seeing health care as a need of a geopolitical area. A health care system is an integral part of the socio-economic forces that create and maintain a viable community. The health care need is met through a system consisting of many functional areas and operating units. Physicians, dentists, nurses, paramedics, hospitals, laboratory personnel, clinics, health centers, intensive care units, custodial care units, and pharmacies provide the functional needs. There must be integration of these functions and a definite relationship between units. This is the proper conceptual framework for studying modern health care services. The new model allows a uniformly structured system to be developed and implemented because it treats the many services and professional personnel as part of the same system. It allows large areas of commonality of service needs to be identified. A feature of commonality is that service costs can be spread over a large group of users, thereby minimizing costs to each. The approach at least brings us close to creating the required characteristics for cost-effective computer applications. The first slide (Slide 1) is a schematic of a

THE COMPUTER IN AN INTEGRATED HEALTH CARE SYSTEM
(SLIDE 1)


Health Center
Extended Care Units
Custodial Care Units
Hospitals
Private Practitioners
Patient Records
Treatment Plans
Drug Data
Central File and Communications Link
Dental Care
Drug Stores
Laboratories
Transportation
Housing
Education
Nutrition
Sanitation
Welfare
Needs, Costs, Benefits, Effectiveness
Regional Health Administration
Appropriations
Budgets

centralized, community based automated health care information system. The center element represents the automated system serving the community. This is not just a hospital system -- all providers have access to those files where a need-to-know exists. Thus, as a patient moves among specialists in the system, each has access to the patient's complete record, and each updates it based on the services provided. The community base provides the opportunity to capture all the patient's health service since he essentially never leaves the system. The three elements shown, Patient Records, Treatment Plans and Drug File will account for most communication activity between the centralized computer files and the remote terminals at hospitals, solo practitioners' offices, pharmacies, etc. I consider these files to be the most important elements of the system and will concentrate most of the remaining discussion on them.

The delivery of quality health services depends on a correct diagnosis and the proper application of therapy. Both the diagnosis and the therapy depend on information systems. The diagnosis depends on information gleaned from a health record; therapy is a function of the latest information available for drugs and treatment plans. Although this information system is essential to quality health care, there has been little effort to structure these data bases as a total information system affecting the productivity of the providers' work and the cost of health services. Before we see major advances in computer applications, the information base serving medicine will have to be structured. Weed was one of the few to recognize some aspects of this problem.[1] Although he did not address the total context of a developing medical science and technology, his work in structuring the medical record is one of the few efforts on the real problem.

The health system is increasingly turning to more organized delivery mechanisms, such as group practices, neighborhood health centers and health maintenance organizations (HMOs). Many different types of providers (physicians, dentists, nutritionists, etc.) will work with the patient on his set of problems and each will reference and update a common record. The traditional records, such as the medical record that has almost as many structures as there are physicians, must yield to a health record that has a non-varying structure and has uniform standards and procedures for making entries. These are also the requirements for establishing a computer based centralized record system. Thus, the social forces appear to be working in favor of automation.

A Possible Structure for the Patient Record

Why does the patient record exist? It's a data bank. It is the vehicle for representing the human being in terms of health care parameters. These parameters are the primary means by which health care professionals can diagnose and plan the management of an individual's health. The purpose of the record, then, is to provide an information base for the diagnosis and management of a patient's health. Clearly, the structure of the record must be responsive to these functions. On the basis of a review of contemporary work on structuring a record, I have extended some ideas and added others. I must say, however, that the result is only intended to represent a point of departure for much needed serious work in this area. The next slide (Slide 2) is a schematic representation of an automated record system and how it can be used.

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[1] L. L. Weed, "Medical Records, Medical Education, and Patient Care," The Press (Case-Western Reserve University, 1969).

Nature of the Data Base

The raw material that is the foundation of the record can be characterized as a set of patient-oriented observables. These observables consist of two basic data sets: one is a demographic profile; i.e. social, economic, vocational, and identification facts. The second is a medical profile; i.e. complaints, examination parameters (including vital signs), and test results.

Essentially, the rest of the record flows from the observables contained in these two data fields. The diagnostician basically rearranges and groups the data to represent patterns that can be identified as patient problems. The result of this is the problem or etiology field of the record. Next, the therapist evaluates the problems and the patient's physical and demographical condition and develops a treatment plan for each problem, forming the treatment plan' data field. At the conclusion of a problem, the therapist prepares a discharge summary. In the proposed record, the discharge summaries are combined with some general patient profiles such as allergies, reactions, immunizations, and operations to form a capsule history profile. These combined data provide the quick summary profile usually desired by a physician. Each of these fields is defined in more detail in the appendix.

Treatment Plans

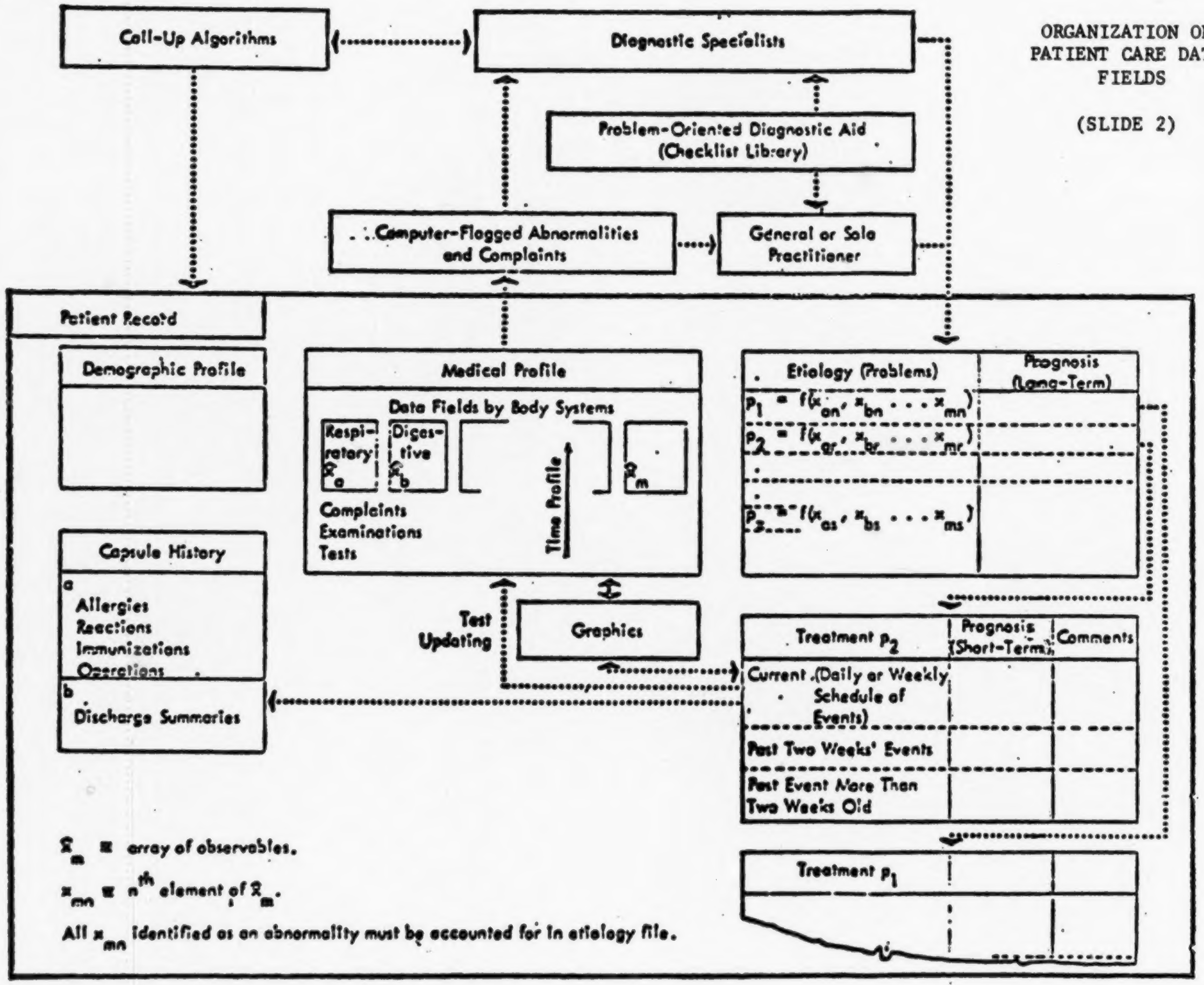
The treatment plan needs little explanation -- it contains the direct and supportive therapy for the conditions undergoing treatment. The automated system will contain a library of these comprehensive care management plans for all major conditions and diseases. The next slide (Slide 3) indicates the categories of information that might be included in a plan. These computer stored plans will not be rigorous protocols that must be used by a physician. The plan will contain alternatives and ranges within each therapeutic category. In addition to indicating the latest accepted best therapy, the plan will indicate current experimental procedures that show promise. The physician will be free to exercise his judgment about which alternatives and how much of the plan to implement. He can make these choices by using a light pen or he can type in his own modifications. Drug selections will be compared automatically with the patient record data and alternatives suggested if reactions, contraindications, etc. exist. As the categories are selected, the computer organizes them into a plan format which, following the physician's review, is transferred to the treatment plan field of the patient's record.

The availability of up-to-date approved treatment plans expedites two other activities within a health care system -- peer review and cost recovery (third party billing). It also has a salutary effect with regard to malpractice suits.

There are some projects underway in this area. Project AMOS at the DeWitt Army Hospital, Ft. Belvoir, Virginia has been developing treatment protocols for use by paramedics, and Beth Israel Hospital in Boston is developing treatment protocols for chronic illnesses.

ORGANIZATION OF PATIENT CARE DATA FIELDS

(SLIDE 2)


Call-Up Algorithms
Diagnostic Specialists
Problem-Oriented Diagnostic Aid (Checklist Library)
Computer-Flagged Abnormalities and Complaints
General or Solo Practitioner
Patient Record
Demographic Profile
Capsule History
a
Allergies
Reactions
Immunizations
Operations
b
Discharge Summaries
Medical Profile
Data Fields by Body Systems
Respi-ratory $\mathcal{X}_a$
Diges-tive $\mathcal{X}_b$
Time Profile
$\mathcal{X}_m$
Complaints
Examinations
Tests
Test Updating
Graphics
Etiology (Problems)
Prognosis (Long-Term)
$p_1 = f(x_{an}, x_{bn} \dots x_{mn})$
$p_2 = f(x_{ar}, x_{br} \dots x_{mr})$
$p_s = f(x_{as}, x_{bs} \dots x_{ms})$
Treatment p_2
Prognosis (Short-Term)
Comments
Current (Daily or Weekly Schedule of Events)
Past Two Weeks' Events
Past Event More Than Two Weeks Old
Treatment p_1

$\mathcal{X}_m \equiv$ array of observables.

$x_{mn} \equiv n^{th}$ element of $\mathcal{X}_m$.

All x_{mn} identified as an abnormality must be accounted for in etiology file.

Drug Files

The average physician writes several prescriptions a day, and probably uses or should use drug information many more times a day. Drugs represent a primary tool in the physician's work. Research has produced a large number of new drugs in the past several years, and will continue to do so. Information concerning the application, efficacy, reactions to, and interactions of these drugs is constantly improving. Although the printed literature, in its numerous forms, attempts to keep up with these changes, there is no single, readily available source of information that can be easily integrated into the physician's routine. As a result, there is reason to suspect that drug usage is less effective than it should be. One might argue that most physicians only use about 20 drugs at any period of time, and are generally well aware of the information about these drugs. Perhaps more accessible information and more confidence in the credibility of the data would lead to a more refined selection of drugs and a much larger library of choices. The computer information system provides the opportunity to economically integrate a drug library into the physician's routine.

Conceptually, the drug file can be visualized as consisting of two basic elements. The first is a set of stored data fields, and the second is a search algorithm that allows the physician to locate the particular data he wants. To illustrate the concepts involved in the drug file, let us discuss one possible way to design the file.

We will start by considering the problem of how the physician finds the particular drug field he needs. If he knows the drug he wants, he can type the English name and presumably all the information about the drug would be flashed on the viewer. Unfortunately, this is impractical since drugs have different usage and associated information depending on the disease being treated. (The term disease is loosely defined here to encompass any condition that is treatable with drugs.)

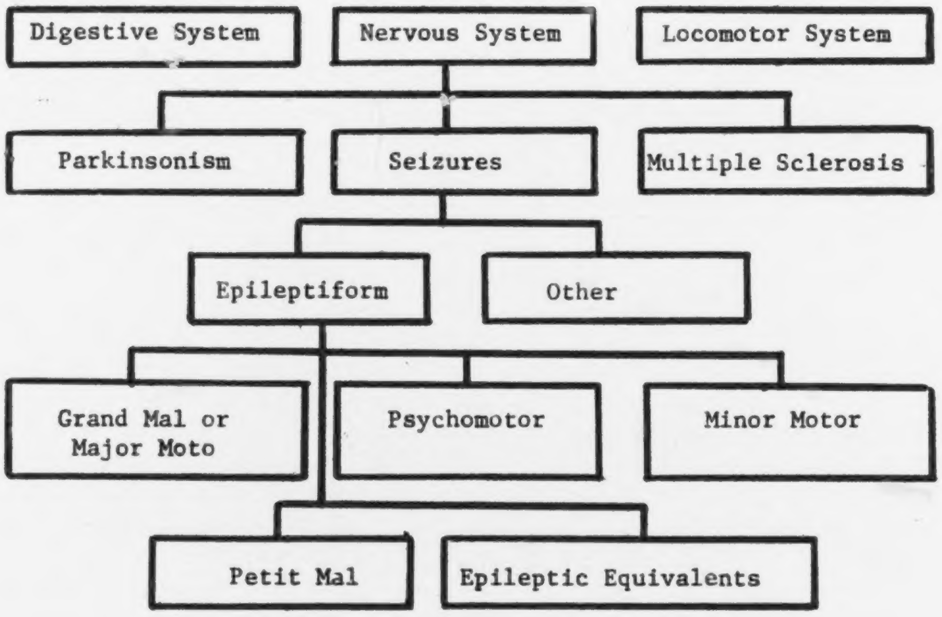
Because of the drug-disease information relationship and the large amount of data associated with most drugs, a more practical approach is to create data fields based upon drug-disease pairs. Thus, the physician who knows the drug he wants to use, but wishes to review the information on therapy, would type in the English name of the drug and disease and, through a retrieval algorithm, the computer would display the appropriate drug-disease data field. The physician who does not know the drug he wants can make use of a retrieval algorithm that allows him to start with what he knows, even if it is general, and narrow down his specification of the problem to the point where a specific drug recommendation can be made. The retrieval algorithm is a decision tree, each level of which consists of an exhaustive set of non-overlapping disease categories. The video would display one or several levels of this tree at a time depending on the capacity of the display unit.

The next slide (Slide 4) illustrates this concept. Suppose the first display consists of the body systems and the physician is interested in the nervous system. He touches the display box in which "nervous system" appears and immediately the next decision level is displayed. Following through, he then touches seizures, which calls forth the display of the next level, then epileptiform and grand mal. At this point, touching the display grand mal presents a display of available drugs as shown on the next slide (Slide 5). If he selects phenobarbital by again touching the screen, he views the drug data

TREATMENT PLAN CONTENTS
(Plan Should Be Structured to Minimize Use of Hospital Service)

Laboratory Tests (initial and follow-on)
Drug Use
Dietary (nutritional needs)
Activity
Utilization of Physiotherapy and Other Therapy
Use of Other Physicians (specialists)
Location of Therapy
Nursing Care
Pre-Discharge Plan (family education, home care, hospital,
    or health center follow-on)
Patient Education (about their illness)
Vocational Issues (need for change)
Need for Dental Care

(SLIDE 3)



Digestive System
Nervous System
Locomotor System
Parkinsonism
Seizures
Multiple Sclerosis
Epileptiform
Other
Grand Mal or Major Moto
Psychomotor
Minor Motor
Petit Mal
Epileptic Equivalents

DECISION TREE

(SLIDE 4)

Grand Mal Drug List

Phenobarbital (infrequent seizures)
Diphenylhaydantoin (frequent seizures)

Alternates:		Other:
Phenobarbital	Meprobarbital Methabarbital Primidone	Phenacemide
Diphenylhydantoin	Mephenytoin Ethotoin	

(SLIDE 5)

Phenobarbital Data Field

Normal Adult: 120-200 mg/day, divided
Range Adult: 50-300 mg/day, divided
Range Children: 1-6 mg/day, divided

AVAILABILITY:

Eskabarb spansule (MFG) 10-12 hr slow release, 65 or 97 mg, $0.50-0.75/day

Stental extentab (MFG) 10-12 hr slow release, 48.6 mg, $0.67-1.35/day

Generic

SIDE EFFECTS:

Drowsiness (relieved by amphetamines), ataxia, paradoxical hyperactivity (children)

Rarely: skin erruptions, exfoliation, dermatitis, withdrawal convulsions (esp. epileptics)

CONTRAINDICATIONS:

Porphria

INTERACTIONS:

Primadone should not be added, may be substituted

OVERDOSE:

Mild	Muscular unsteadiness, drowsiness, dizziness periods of excitement w/ delusions + hallucinations, BP + RESP adequate + reflexes operative *** conservative, supportive therapy
Severe	Coma w/ CV + RESP difficulty, vatiations in temp + pupil size, pneumonia may develop*** energetic treatment to maintain adequate resp, circ, temp + prevent pneumonia, removal from GI tract

PRECAUTIONS:

None

(SLIDE 6)

field display shown in this slide (Slide 6). All this is done in a matter of seconds.

As mentioned earlier, there cannot be one data field per drug because a drug may be used in very different ways to treat different diseases. Also, the alternative drug may be used in a different way than the first choice, and would require its own field, or it may not. Therefore, though each drug-disease pair may not require a unique field, each pair will require a distinct field. In this slide, (Slide 6) I have shown a structured distinct field for phenobarbital. It is fairly elementary as it stands. There undoubtedly will be a need for a much more refined structure. For example, under dosage, we may want to add entries for pregnancy and nonstandard dosage. There may be special category entries for new or controversial drugs that display literature abstracts, give references, or might even present detailed literature.

In its final configuration, this drug file would be tied into the patient record file. This interface would be accomplished by a querying algorithm that would automatically check any drug being considered for patient reaction or interactions with other drugs in active use by the patient. Simple structured messages would alert the physician or druggist to these facts. Examples of these messages might be: "Patient Allergic" or "Medication Chosen Reacts with Current Medication (drug name)".

In addition to inserting this information into the patient's record, it will be possible for the physician to transmit the final prescription selection to a terminal at the pharmacy of the patient's choice. Thus, the outpatient prescription process will eliminate the cumbersome mechanisms and numerous handlings now involved. With the transfer of the prescription order to the pharmacy, the automated pharmacy system takes over. This system was discussed in an earlier paper.

Conclusions

In other fields, the science and the people practicing it expanded together in a relatively free environment. In contrast, medical science has had to grow within an established professional community and framework with considerable inertial resistance to change. Although the professional has tried to adapt, it has had to rely on a blend of old techniques yielding new products. The result has been less than satisfactory to everyone. A combination of more acute awareness by physicians of these problems, more governmental interest in improving health services, and a better comprehension by the general public of both therapy and what constitutes a realizable level of medical care, have brought the area into technological focus. An attempt to find computer applications in medical care is one manifestation of this tide of concern.

Controlling costs and improving the quality of health care are not simple problems. The first-with-the-most approach will not produce viable results, nor will a purely technical solution. We need more systems analysts with their broader views working on the solutions than systems engineers. We need a better understanding of the cost/benefit relationship between automation and human-effort in the labor intense health care system. And, finally, this perspective must be developed for more typical health care systems than past efforts.

APPENDIX

Explanations of Patient Record Data Fields

Demographic Record

The demographic profile represents a distinct field of information that will be called out by many users either in combination with some date in the medical profile or alone. Its structure is relatively straightforward, requiring sub-routines that provide discrete sections (such as patient identification factors) to be called on demand.

Medical Profile

The medical profile is the most difficult part of the redord since it usually represents the major picture of the patient. These data are also direct inputs to the diagnostic process. Diagnosticians are organized along specialty areas, with even higher order of specialization within these areas. The current ideal case for specialists would consist of exclusive data sets that completely served each specialist. But this view-point is probably valid only if one wanted to adapt to the existing system. There is no evidence to suggest that the current informational base used by specialists is ideal. The existing system is inefficient. Symptoms and problems are not uniquely correlated; therefore, storing data along specialty lines could result in considerable redundancy since there are no unique allocation schemes. Furthermore, the specialty areas are not related to discrete body systems, but usually encompass several systems. A patient's health, however, is a function of the state of his body systems. Conditions and disease affect systems, and problems manifest themselves in systems. Since, in effect, the particular record was meant to display the patient's health, it would appear that the fundamental data field consists of a group of subfields, each of which describes the condition of a body system. In many uses, there is already a one-to-one correlation between specialist areas and body systems. Gynecologists, dermatologists, and eye and ear specialists are examples of this correlation.

There may be a need to structure some subfields along specialty lines. For instance, pediatrics is a special case. Perhaps the files of all children under twelve will require a totally different format based upon providing maximum responsiveness to the needs of the pediatrician.

For the near future, it would appear that provisions must be made to identify many of the specifics about how patient examination and laboratory test data were obtained. For instance, in measuring blood pressure, there are many combinations possible from the parameters involved such as patient position, part of the anatomy tested, instrument used, and identification of the professional making the test. This situation puts a premium on good coding algorithms for data storage. An example of the variation in data that can be involved in a blood pressure test is given in Figure 1. A simple coding technique is also illustrated.

Test: Blood Pressure							A	
Code					Patient Position	Anatomy Tested	Instrument	Administrator
A	1	1	1	1	supine	right arm	type x	nurse
A	2	1	1	1	prone	right arm	type x	nurse
A	1	2	1	2	supine	left arm	type x	physician

Figure 1: AN EXAMPLE DATA MATRIX

Etiology Field

In the process of a diagnosis, a physician transliterates the set of complaints and abnormalities into a set of problems. In this same process, he also transforms the set of body system observables presented to him in the medical profile into problem-oriented observables. The etiology file merely preserves this transformation. It identifies the specific complaints and abnormalities with a problem and presents a visible portrayal of the diagnostician's work. Observables that cannot be ascribed to a specific problem will be listed under an unexplained entry. When completed, the etiology field will contain the entire set of complaints and abnormalities originally identified in the medical profile. The combination of a problem structure and an observable accounting system will provide both the diagnostician and therapist with a more effective vehicle for pursuing their tasks.

Treatment Field

The treatment field will contain the total therapy schedule for the patient. Each problem will have its own specific treatment plan. A treatment plan data field will be divided into an active and inactive section. The active section will contain a one-day or full week's schedule of events for the patient listed in chronological order (the time period will be determined by experiment during the project). For example, if a drug were to be administered every four hours, the schedule will show it entered at 8, 12, 4, etc., rather than "every four hours". An event schedule provides an objective oriented plan displayed as a time profile. Experience with this type of plan has shown it to be a motivating factor to the professional staff and a cause for increased productivity.[1] The active section will also contain the record of the past two weeks' schedule of events and the results of these events, such as important observations, results of physical examinations and tests, temperature readings, etc.

The second part of the problem-treatment file will consist of the treatment and chart information that is more than two weeks old (again, the time period will be determined experimentally). This file will be stored off line on tape since it can require a large storage capacity.

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[1] Conversation with Mr. Robert Baker, Texas Institute for Rehabilitation and Research.

The utility in storing these data will require research since the future importance of a historical vital-sign profile is not well known. Some data must be preserved. The question centers on the sampling rate used in extracting the data to be stored. For instance, if temperature has been taken every two hours, should every measurement be stored, only a morning and evening measurement, once a day, range for the day, etc.?

Discharge Summary

The problem-discharge summary is an encapsulated inventory of the problem. The summary contains the original diagnosis of the problem, the final diagnosis, summary of treatment, any significant facts, and prognosis. It will be stored as a distinct part of the capsule history.

Capsule History

The capsule history file will serve as a record abstract and will provide the professional with a quick overview of the patient's medical history. It will contain data on chronic illness, immunizations, allergies, reactions, and a chronological listing of problem-discharge summaries.

3. SPECIAL ADDRESS

WIRING UP THE WOBBLING WORLD

Andrew A. Aines
National Science Foundation

It is an honor and a privilege to be invited to this splendid campus to share a few thoughts with such an eminent group of men and women dedicated to the enlightened task of maintaining and improving the health of all Americans. I salute the planners and sponsors of this conference who have worked so hard to make it possible. I know that each of you will contribute liberally to its success and that when you depart, you will carry away with you the warm feeling that you have both made an important contribution and that you have left your associates richer intellectually for having been here.

Meeting again with George Hager and Paul Olejar, who have done so much to improve the theory and practice of chemical and pharmaceutical information-processing over the years, brings back many memories.

We were then the young Turks, discontented with the status quo, dedicated to the lofty objective of restructuring the way the nation and the world should structure its chemical information programs. Specifically, we quarreled about the way to modernize chemical notation systems. But we recognized that this was a small, though very important sub-system. In the early sixties, we began to perceive that a new era of information was drawing nigh and that what we were doing was of growing importance. We hardly talked about the coming cybernetic revolution. Marshall McLuhan had not flashed across the skies in meteoric fashion. David Sarnoff had not made his pronouncement that the new building block of society is information. Fritz Machlup had not yet written about the arrival of the great knowledge industries. Peter Drucker had not yet put forth his pronouncement that the impact of cheap, reliable, fast and universally available information would easily be as great as the impact of electricity. Daniel Bell had not yet predicted that the United States was on the verge of becoming a Post Industrial Society with the information and communications industries in the center stage.

Nevertheless, we could feel that a new tide was sweeping in and we were on the crest of a wave. We were reading the statistics that came to be subsequently referred to as the "information explosion." We were aware of the imminent arrival of a host of new technological advances in computers, telecommunications, reprography, micrographics, publishing, and more. We understood the potential gains that might be registered by wise harnessing of the new technologies in coping with the flood of knowledge that is a hallmark of this era. We began to see the traditional tools of knowledge-handling we inherited from the past in transition, often in disarray. We were full of pride that the field of drugs and chemistry would be in the vanguard of this great movement.

A decade has passed, and I guess we are still proud to be thought of as young Turks, still striving to comprehend the mysterious force sweeping us forward, still trying to find "handles" that we can grasp, and still trying to profit from our experience, especially our mistakes.

It is my pleasure this evening to share a few insights and conjectures with you. I hope from my rough-hewn diagnostic exploration, you will be stimulated to interact with me. Wistfully, I hope that I will be able to enrich your own perceptions and expectations. If they match my impedence, so much the better. If they clash, so be it.

To begin with, let us take a brief glance at the era. It has been ushered in by a gaggle of revolutions or near-revolutions in science and technology, in education, in moral values. There are so many of them that we are unable to distinguish cause and effect. We now talk about crisis management as the mark of solvent governments and institutions. Problems - most insoluble - come so quickly that they tend to replace and transform earlier ones; they are rarely solved in a logical, satisfactory way. Many of the institutional pillars of society are in disarray. The discontinuity between the life styles of the yound and old is often frighteningly dramatic. Population pressures, environmental decay - but why go on? Every person in this room can add a few of his or her choice candidates to the list.

Although you would hardly detect it from reading or viewing the media, there are some entries on the other side of the ledger, entries that are positive in nature. The vast majority of our people continue to work hard to make progress. There may be more people hungry than there should be, but at least in our country more people are being fed, clothed, housed, and educated than ever before. I will not gild the lily or claim we are even a light year close to a utopia, but the University, though a bit bloodied, still stands; the pharmaceutical community can proudly talk about new drugs, new techniques and procedures, and other breakthroughs that have revolutionized and advanced chemotherapy to new heights. There are people in hundreds of other fields, literally, that can proudly point to advances and gains to make the human condition more bearable.

But it should also be reported that somehow the interaction of technological breakthroughs in many fields results in unexpected biochemical socio-economic-like action which at times creates unwieldy problems. To solve one problem, we unwittingly can trigger off yet others. I am not sure if it is fair to blame the breakdown of moral values on the Pill and other prophylactic technology, but somehow some stubborn part of my brain keeps grumbling that they could be contributing. While I hasten to reject this as a generalization, we all can cite others that raise so many emotional hackles, like environmental pollution, stagnating cities and traffic, strip mining, and many more. As each technology expands, often without regard for its cumulative effect, we seem to be playing a form of Russian roulette, like the kids who raid their parent's medicine chests for pills, mix them up, and take self-destructive potluck by ingesting them. As you gather, I am now discussing the need for technology assessment, which, it seems to me, is a long overdue task for civilized society.

Recognizably, this is a morose picture of the scene, but no special insights are needed to recognize that public anxiety is bordering on neuroticism, so let me add this all up in this prefactory note by admitting that this is not a placid era, but one of grave disequilibrium. It is a wobbly world, indeed.

As I was writing this paper, the massive strike of communications workers broke, hence it would be difficult to convince any objective observer that this is the crowd I have in mind when I talk about "wiring up" the wobbly world. Rather, I harbor a deep belief that we are going through some kind of an information-communication upheaval that has some traditional and some unique characteristics, that the introduction of new communications into an unsettled world is bringing on a condition similar to spastic fibrillation, and that we will approach a steady state only when we have mastered the indigestion.

Consider: Every person in this room is a product of the kind of conditioning that comes with the Gutenberg inkprint medium. I might add the aural medium, radio, which admittedly does not equal books for intellectual transmission, except on growingly rare occasions.

Consider: The flow of new scientific and technical knowledge in a variety of forms is akin to a tidal wave that increasingly robs us of the assurance that we can be confidently knowledgeable of everything of importance that happens in our own and almost any field. I do not believe that there is general awareness of this phenomenon, although we are willing to acknowledge that the half-life of a professional's knowledge gets shorter and shorter with each passing year and that formal education consequently must be spread over a person's active lifetime.

Consider: A great new knowledge industry, as previously mentioned, is beginning to grow. It is important to realize that the information process is going through a process of institutionalization. Creating and operating a large computerized information system is a "big" business. It is my estimate that the cost of scientific and technical information handling by the Federal agencies alone is over a billion dollars a year. There is not a university in the world that trains men and women to create and manage programs and systems of this magnitude.

Consider: Several years ago, the Pierce Study on Computers and Higher Education, commissioned by the President's Science Advisory Committee, advised a rapid and universal action by universities to teach students how to use the computer. Hardly anything happened. Sure, many of the more affluent colleges moved into the use of computers for administration and research, but nothing as dramatic as the Pierce Panel suggested has been achieved. The problem is not the lack of money alone, although it played a major part. While we have trained many thousands of programmers and magnetic tape tenders, by no stretch of the imagination can we claim that more than a few thousand people in our country really know how to use computers in a creative fashion. Like the cynic said, "We are moving into the use of fourth generation computing machinery with first generation managers."

Consider: Most of us are well-schooled to a built-in attitude that good information is scarce - and in many respects the condition still prevails. But, as I mentioned earlier in another connection, we are in an age of information overabundance. The trouble is, most of us are still acting out the script of information paucity; although the information warehouses are bursting at the seams. As individuals, we tend at times to hoard information largely because that is the way we are trained. A good case in point is the Pentagon papers. Did you know that there is a large professional society of classifiers? Our patent system is not organized to make information pertaining to invention easy for the public to get. It is almost a closed system. Congress passed a Freedom of Information Act a few years back to shake up the Federal agencies, yet Congressional committee chairmen have been known to maintain near tyrannical control over the information apparatus in their groups. All you have to do is talk to members of minority parties in Congress to see what I mean. Many scientists play the information poker game close to their vests. Industrial espionage flourishes because of the monetary value of information, but also because its a great game to play.

Consider: There are extraordinary developments in information and communications technology. Think of all of the telephones, radios, television sets, and other electronic equipment already in our homes, schools and offices. As CATV, electronic video recording, zerography, and micrography, singly and in combination, begin to invade our offices and homes, think how much more our sensory capabilities will be extended. As the picture telephone makes it possible again to bring people face to face electronically, as EVR for home TV sets returns time control to the individual, as cable TV significantly increases the number of channels and selection of programs, as electronic newspapers become viewable on home TV screens on demand, as direct transmission by satellite of programs to home and community antennas moves towards reality, as the small home computer or residential terminals connected to larger central data utilities become available, as lasers to transmit mail and data and improve computer storage become commercial, as holographic picture transmission for business and entertainment emerge from the laboratory, and as computerized networks interconnect information nodes for a wide variety of users - just think of the impact on the way we live! As these things happen, I contend that we will realize that the communication revolution is really less one of technology than a revolution of knowledge and the availability and utilizability of that new knowledge.

Consider: For those of us immersed in this emergent business, there is something of an Alice in Wonderland feeling. Here comes the technology, here are the great needs of society for information and data; information to solve problems, information to advance knowledge, information to make the decisions we face daily, information to heal our sick, information to govern effectively, information to operate our technological machine, information to control crime and promote justice, information to cleanse our environment, information to promote peace and tranquility on our streets and among nations, information to control criminal drug traffic, information to enable necessary change in our attitudes and our institutions - the list is endless. We need the ability to bank known knowledge in such a way as to organize it and call it forth out of the vaults much more rapidly and intelligently than ever before. Yet our success in doing so has been piecemeal and hesitant. The fearsome cost of not solving the problems of decaying cities, of clogged highways, of a creaking educational system and so many more needs, are so great that whatever we may be called upon to invest to improve the information foundation and conduits needed to facilitate change would be a comparative pittance. The investment, however, calls for much more than money, I remind you.

McGeorge Bundy in a keynote speech to an international symposium on the management of information and knowledge noted: "The problem is that in most if not all spheres of inquiry and choice, quantities of raw information overwhelm in magnitude the few comprehensive and trusted bodies or systems of knowledge that have been perceived and elaborated by man...not only of knowledge systems with predictive value, but also of information systematically organized to yield benefit of comprehensive description." He asks: "Where does the novice mayor turn to comprehend the dynamic relationships between transportation, employment, technology, pollution, private investment, and the public budget, between housing, nutrition, health, individual motivation and drive?" In that same speech, Bundy strongly advocated a powerful environmental quality information system international in scope. I happen to agree with Bundy, and ruefully admit that the government is fumbling its way towards such an organized system. Bundy made another statement in his talk that ought to be framed and placed on the wall of every person who is a modern rationalist and advocate for progress. He said, "In the hands of men of powerful and scrupulous intellect, this modern tool - the computer - can help us define the facts, but not 'an' answer or 'the' remedies...Societies can become paralyzed over a plethora of facts and the absence of obvious conclusions. Or they may freeze when the indisputable facts and necessities offend received values and conventional wisdom..."

Consider: A pre-election statement by President Johnson (Drug Research Reports, November 11, 1964) on his health goals put dissemination of drug information on a par with the discovery of new information. LBJ said a system of drug information centers would be "essential" to a Democratic Administration's health program. The same article stated that the American Society of Hospital Pharmacists proposed that it would identify hospitals in which centers would be feasible, organize essentially a national network of these beginning centers, then develop a pharmacological classification code that could be used in most of the centers. The code was to be built on the numerical system used in the American Hospital Formulary Service. The code would be used in developing electronic data processing and indexing systems, with a standardized system usable by all contributing hospitals.

In the same Drug Research Report, some interesting comments were excerpted from a speech by Don Francke of ASHP. One of these caught my eye. He said: "In the field of drug information, tens of pharmacists could serve the needs of thousands of physicians serving millions of patients...The social significance of establishing drug information centers in teaching hospitals is far greater than providing drug information service to physicians; through such centers could be developed simultaneously a program to audit drug therapy in the major teaching hospitals..." So much for the comments of President Johnson and Don Francke. How much progress we have made since these promises and predictions were cast, I leave to you to evaluate. Even with the best of intentions, the gulf between promise and accomplishment inevitably yawns and yawns.

Consider other glitches: Many people who need information and data badly show little interest in changing the size and shape of the net they use to get it. If I remember his law correctly, Calvin Mooer pointed out that if it takes any special effort to obtain information, people are seemingly loathe to invest such energy. The reluctance of many people to scrap their prejudices extends to the way they get and handle information. This is important to dwell on because this truth hangs over the head of all those who presume to create new mechanized information systems for people. Despite the appearance of a torrent of plans to improve information systems for scientists, engineers, technologists, administrators, and others - it is a rare incident when the plea for improved system performance comes from the grass roots. Moreover, the kitchen midden for discarded information systems, many computerized, is full of rejects. Many of these could have been successful, if the users were willing to change their information practices sufficiently to make them work. It is also true that many information systems were technically inadequate, thus doomed to failure, but this is only part of the story, the part that gets the publicity.

From what I have said up to now, you can add up a few facts and draw a few conclusions - the technology is here; the information bank bulges; the information infrastructure is growing, but has not yet reached a high degree or requisite of professionalism; the need for good information and data for the individual and society is soaring; information is now big business and will take center stage as we advance into the Post Industrial Era; communications contributes to the health and problems of society; as individuals and as a society we are all being "re-programmed" to the more sophisticated use of knowledge and the knowledge apparatus; and society has not yet made the kind of investment needed to take advantage of the new tools.

Although we have not achieved the kind of potential I attribute to the communications revolution, I cannot help but remember the truth of Nathaniel Hawthorne's observation when he advanced the view that "a man's bewilderment is the measure of his wisdom." Certainly, the ferment we are going through, including the surge of new communications and information-processing technology that pours out of our laboratories, the cutting and trying on of new information system garments, the experimentation with networks and cost-sharing, and the uneasy marriage of conventional and unconventional information systems, the growing concern of developing and some developed countries that they have no black box to plug into, and the international complexion of the infodata turbulence all contribute to man's "bewilderment". We can draw some comfort too from the word's of the anthropologist, J.D. Unwin, who said, "There is no trace of any display of productive energy that has not been preceded by a display of expansive energy" that we can see.

It was John Dewey, the famous educator, who once pointed out that there is no such thing as status quo in a modern civilization. If he lived today, he would have so much more evidence to prove his point. And because the name of the game today is change, in my judgment, if we want to bring a measure of some stability to this wobbling world, we are going to have to improve our ability to communicate. If we want to control our destiny and keep this powerful technology under control, we will have to do more long-range thinking, more intelligent formulation of options so that they can be understood by the elite and the public, and we must take steps to guide the course of events along a chosen path, which as the scientist, Robert S. Morison, urges "must become as exciting and rewarding for the best minds as is the present pursuit of basic scientific knowledge."

To achieve a high measure of success, I believe that the best thinkers in the United States and the world must address their thoughts to the issue. I disagree with the theoretical possibility of the resolution of the problem via obscure and random marketplace action. I would hope that our leaders - not excluding the professional who also calls himself a pharmacist - will work with the Hagers, the Olejars and the rest of us, who believe that the world of communications, information processing, and the wise use of knowledge are one and indivisible.

This is my hope, expectation and goal. I am sustained by a thought in Carl Sandburg's poem, "Washington Monument by Night" in which he reminds us that, "The republic is a dream. Nothing happens unless first a dream."

II. WORKSHOPS

1. COMMITTEE REPORTS

WORKSHOP A

THIRD PARTY PROGRAMS

Any of the third party systems involved has an immense volume of claims and to typify the total problem, I'll use the proposed Medicare program for out-of-hospital patient prescriptions as an example. We are talking here about one to one-and-a-half million prescriptions a day in a dynamic flow and with an overall ($4.00) unit value. Very early in the studies for this program, it was decided that any paper flow in which we wanted to gather significant data would inundate us simply by the number of rejections you would expect on a normal program, i.e., 4.6% that we presently experience in the Social Security Administration program for retiree beneficiaries. We keep records on approximately two hundred million wage-earners. Our tape library consists of approximately one hundred eighty thousand reels of tape. We even have a program to find out which reel of tape to use. However, this can and is done in a very business-like manner in our shop. The cost of administration of this program (I'm talking about the survivors' benefits and the retirees) is two percent.

When we look at Medicare, the cost of administration rises significantly. There is a difference between the cost of processing physician's services and hospital services, but there is no significant difference between the two, although the cost is quite higher than that for retirement beneficiaries. This is due to the fact that we have to rely upon other people (intermediaries and carriers) who have different degrees of sophistication and/or EDP equipment and usage. Some of the things we talked about are as follows:

1. There is an enormous volume that can be expected to flow through any of these third party systems. Of course, we are not talking about the total health care picture, but simply of the transmission of drug data for repayment by third parties. We are not talking about capturing data for review of contraindications or potentiation or any of the qualitative aspects. The qualitative review can be done as a subsidiary program or as an after-the-fact program.

2. Each of these transactions is a small transaction and, if you use a clerk for utilization or review purposes, the cost relationship would be absurd. We are talking about an average claim of $4.00. If we spent more than a minimal time on it, it would be out of order as regards to cost.

When we first started talking about a possible Medicare drug program back in 1967 and before, we projected a program of four hundred million claims a year and accepted five percent as an acceptable figure for the cost of administration. This would have been about $.20 per claim for the first year which we expected to drop down to about $.12 or $.13 after the first year. The average cost of the prescription has risen since then. Approximately five years will have passed by the time of the inception of this program and its implementation.

The need for mechanizing or using computers to process claims has not only become more and more desirable, we feel it has become necessary. I think anyone in the third party area will agree that there are different degrees of use of computers, but the most desirable feature that we found in processing claims is that there should be error-free input.

When we first started talking about this concept a number of years ago, people said that we wanted to put a man on the moon, and we said indeed, we did. Well, men have been put on the moon, and we do have today an error-free type of input which several manufacturers now have in production to help the commercial field with similar problems. A number of companies such as IBM, National Cash Register, Pitney-Bowes, and others have adopted this concept as the means to pick up their data error-free.

If there is a dynamic flow of a million prescriptions a day and a five-day work week, with a ten percent reject rate, we would have fifty thousand rejects a day which somebody would have to review and either send back, or not pay, or delay payment. We would not like to do that. We would like to follow the pattern of PCS and others and make prescriptions payable within fifteen days, and we feel that this will be done.

We are not geared to, nor do we pretend to be able to tell the physician that he should use the proper drug, at a proper time for the proper use, but we will use one form of utilization review and that is to detect over-utilization per se or over-prescribing. In other words, by developing a physician's profiles, drug profiles for the patient, and drug store profiles, and meshing these three we can find out quite a bit about what is going on as far as program administration is concerned, and that is our primary job.

Of course, there are other elements that we will collect during this data transmission which will be given to other agencies within HEW, for their use in teaching, continuing education and other means of upgrading the practice of medicine and pharmacy.

4. To be efficient, we feel that there should be an extremely low cost for this data collection. We have been assured by one of the major -- perhaps the major electronics manufacturer -- that once the data is collected, in the terms of which we are speaking -- i.e. four hundred million claims or more a year -- that the cost of manipulation of this data is from one-half cent to one cent per transaction. This does not include the cost of the computer itself nor the cost of postage -- we are talking about the manipulation of data.

Using the type of program that we have envisioned, we feel that we can immediately detect trends in any sort of abuse or over-utilization situations. We have also taken into account some of the trends that are developing within pharmacy, such as the use of family record systems. We expect that some of the hard copy that will be developed as a byproduct of the data input will be used to supplement the family record system.

5. We talked quite a bit about some of the other uses of a terminal device or data collection devices and one of those was the re-ordering from the wholesaler, inventory control, etc. All of these things are possible as supplementary programs, using a particular device.

6. Depending upon who uses or controls the use of the device, the cost of all these users would be prorated. We can see how many of the third party, government or non-government programs can have data sent to a collection site and either processed or simply collected and then sent

to SSA or Medicaid or any other third party as the case may be, with each paying part of the cost. If the pharmacist uses the terminal to control inventory or to reorder, he would pay part of the cost.

Vic Morgenroth did a tremendous job in stating the problems involved with third parties today that use a paper system. He gave us a typical day's work as an example. He said that a nursing home called in a series of fifty prescriptions and it took four hours and ten minutes to prepare and complete the forms involved, and fifteen minutes to fill the prescriptions. I think that this is an excellent example of what is faced by pharmacists today unless a more sophisticated means of collecting, disseminating, and processing data is produced. This is one of the main reasons that we have shown a preference for a data input device that will collect data error-free, quickly, and at a low cost.

Our particular job at SSA, at this time, is to collect data, process it quickly, and pay the pharmacist quickly, while detecting trends and abuses. That is our job. I suppose that's the job for any third party program; I think that the ends that we have at SSA are certainly those of any other third party program.

System Requirements Defined

As I've said, we talked about many things, but the real subject of our group was the data requirements necessary for processing third party claims, and the following items are those which the panel unanimously agreed upon. As stated before, these items were decided upon by members of diverse groups representing not only government agencies but also private parties, state organizations, etc. Basic data requirements are the identification of patient, physician, and pharmacy. There should be a transaction number. The drug should be identified, perferably by a code, and data would be needed on refill indication, date of dispensing, quantity dispensed, number of days supply, and charge. Finally, the payer or insurer must be identified.

Some comments: The National Pharmaceutical Insurance Council's vendor number certainly is one that everybody can use in the proposed system. Naturally, there should be a drug code number. We decided that it should be the Food and Drug Administration's National Drug Code, if for no other reason than the fact that it does exist, it is widely accepted and will probably be mandatory by the time our program goes into effect. The patient identification number will, of course, be the social security number.

For the physician's number, we have shown a preference for the social security number. The AMA also has a list of physician numbers, but we were not sure that this is a complete list. We are going to communicate with the AMA and find out what their preference would be, i.e., which system they would prefer to use. We will work in conjunction with them in determining what the physician number should be because all of the plans, whether they be private, government, state or what have you, require a physician number.

It's important to SSA, and I'm sure it is partly true for the private third party plans, that each of these inputs be given a standard number, or a common number of characters, whether numeric or alpha. And we agree upon these various number of characters. Of course, this will be available to you after the proceedings have been printed. The SSA Medicare drug program will use a standard set of characters; whether the other programs will do so remains to be seen.

I would like to thank Mr. Olejar and Dean Hager for inviting Mr. Higgins and me to participate with this panel. We enjoyed thoroughly the input and by-play of the various participants. I think that this meeting has provided an opportunity to show that there can indeed be unanimity in the selection of elements to claims processing that are needed and that they can be agreed upon by all persons concerned. This should help to finish the development of a multi-program terminal device.

Riley J. Jeansonne, Reporter

Committee Members:
Joseph Higgins
Jack Fay
Victor Morgenroth
Michael Ripsman
Raymond Terkhorn
Frank Yarborough

WORKSHOP B

DRUG DATA

Thank you, Mr. Chairman. I think it should be noted that the Committee put in a thoughtful, intensive, and creative effort. I trust my interpretation of their thoughts will be correct. Workshop B focused on the contributions a computer-based information system could make to pharmacy practice in the context of direct contributions to patient care. We felt the pharmacist can contribute most to health care services if he directs his efforts to advising the physician and patient on safe and effective drug therapy. For this purpose a properly designed information system would be highly desirable and a computer-based system should be considered. The system should be designed to give the pharmacist the information while the patient is with him rather than on the next visit, if any, after the prescription has been filled.

The system should help support two major functions of the pharmacist which are separated into those directly involved in patient care activities and those which are indirectly related to the role of patient care. The direct functions include the dispensing of medications; and such auxiliary tasks as Rx usage control, drug monitoring (comparing current orders with previous to look up allergies and interactions), and health information (advising where information can be obtained on drug abuse and poison control). The indirect functions which account for an estimated 40% of the pharmacist's time, include such tasks as handling accounts receivable (third party), accounts payable, inventory control, merchandising, personnel management, financial management, and civic service.

Most of these functions we felt offered great potential for computer-based information systems to aid the pharmacist in providing health care. Third party payments would, in our opinion, come under accounts receivable.

There are two categories of data needed to perform the direct functions. These are (1) situational data on the patient and the drug order, and (2) resource data. At this point, to clarify what follows, I would like to define what the direct patient care functions mean. I take the liberty at this point to express in my own words the committee's understanding of the categories.

Under dispensing fundamentals, we're talking about providing accurately prepared and labeled prescriptions. This would involve getting the right form and strength of the prescribed product, typing the names and dates of patients and physicians, providing clearly typed directions for dosage administration, appropriate auxiliary labels, and, of course, the correct count or volume of the drug. Under prescription usage control, we refer to the pharmacist assuring good drug therapy by checking the patient's comprehension of drug usage, adequate explanations, if needed, of dosage instructions, adequate explanation of cautions and storage conditions, and recording the fact that the prescription was dispensed on some sort of family medication record. Under over-the-counter drug usage control, we refer to the pharmacist's activities in advising patrons on the use of self-medication products by giving the patient information on the choice of product, by pointing out the limitations of self-therapy, by referral to the appropriate sources of professional help, if needed; and recording purchased over-the-counter drugs on a family medication record.

Under drug monitoring, we refer to activities related to detecting and solving problems involving incompatibilities and adverse reactions through the use of family medication records, through recognizing or seeking patient-provided clues and using all the other sources of professional knowledge available to the pharmacist through printed material or other types of information which we refer to later as resource data.

The system which would help fulfill these objectives of professional practice is outlined below:

MD's office enters Rx into regionally organized data bank
Patient goes to pharmacy of choice
RPh queries data bank for new drug orders and current drug
  history (including allergies, drug interactions, etc.)
If no history, obtain Rx
If problems, consult MD
When Rx is OK, have terminal prepare label and initiate
  payment process
Drug order is filled by a technician under the pharmacist's supervision
Pharmacist advises patient about Rx and answers patient's
  questions.

The physician's office staff enters the prescription into a regionally organized data bank. The patient goes to the pharmacy of his or her choice. The pharmacy queries the data bank for new drug orders and current drug histories, including allergies, and drug interactions. If there is no history on file or if after study of the medication record, there are problems in the drug order being placed at this time, the pharmacist consults the physician, not necessarily through the computer, but perhaps by a telephone call. When the prescription order is correct and the necessary modifications have been made in the computer file, the label is prepared on the computer terminal. At this point, we can take advantage of using technicians under a pharmacist's supervision to perform the mechanical functions of actually filling the prescription itself. At the same time, the payment process is initiated. This is where this system articulates with third party payment systems. When the drug order is filled, the pharmacist then explains the use of the drug to the patient, and answers any questions on over-the-counter drugs or health information which the patient may have. That, in very general terms, is how we see these functions being performed.

The first type of information necessary to implement this system involves situational data, i.e., patient and drug order data relating to a specific transaction. Situational data includes: identification of the physician, pharmacy and the patient, the patient's demographic data (birth date, sex), the patient's drug history and allergies, third party plan identification, the diagnosis and the prescription itself, i.e., the drug, directions, quantity, dosage, form, strength, date, etc. Also needed are flags to indicate that: an order was written, the prescription was filled, the date the order was filled, the pharmacist and technician who performed the activities, the lot number and brand of drug dispensed, refill authorization, price, quantity, and that certain actions were performed by the pharmacist (such as patient or physician consultations). These indicators were thought to be desirable to permit reviews of drug utilization and the pharmacist's effectiveness in health care.

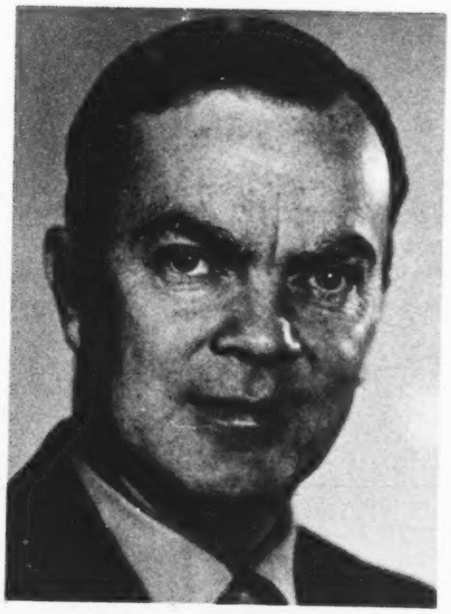
Under the heading, resource data, we decided to exclude the medical literature on the grounds that including such voluminous data is beyond the scope of the present system's objectives. The resource data needed for the system includes: drug names and codes, (we thought for a number of good reasons which time does not permit us to go into this morning the best example of a useful drug code is the American Society of Hospital Pharmacist's Drug Products Information File), a centrally prepared data bank on adverse reactions and drug interaction data which would be limited to those that are clinically significant, cautions and warnings for the patient on the use of the drug, and data on the restrictions involved in dispensing medications such as those for controlled substances or investigational drugs.

Unresolved questions concerning such a system include its price/benefit ratio, who would pay for its implementation and the thorny problems of confidentiality and invasion of privacy.

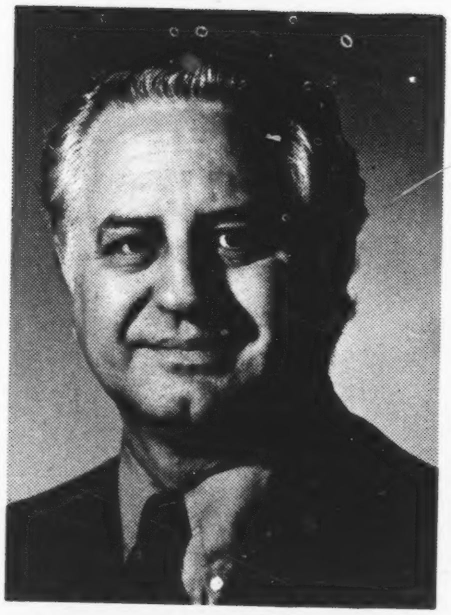
Well, this is a quick sketch of a complex subject. It deserves considerable further discussion between all parties concerned, particularly pharmacists from all areas of pharmacy and systems designers. They need to hammer out acceptable trade-offs. It was recognized that this approach faces many difficulties, primarily legal and economic. But also it was anticipated that in making trade-offs, a systematic and objective analysis will reveal the merits of the system. Laws can, with difficulty, be changed. If the need is urgent enough, funding can be found. If the system really helps pharmacists, I think they would be willing to pay for a fair share of the costs. As a final point, we would like to stress that many of the data uses, such as third party payments and drug utilization review, which have received much discussion at this Conference, could be obtained as a by-product of the patient-care system outlined. We believe emphasis on how computers can help the pharmacist provide better health care is the appropriate issue and is the perspective from which this Conference was conceived. Mr. Chairman, this report is respectfully submitted.

Raymond Jang, Reporter

Committee Members: James A. Baker
James L. Carmon
N. E. Cooley
Fred M. Eckel
Paul D. Olejar
Margaret K. Park
Edward Patula
Mary Jo Reilly
Winifred Sewell



Joseph Higgins
Moderator - Workshop A



Riley J. Jeansonne
Report Committee Chairman

Paul D. Olejar
Moderator - Workshop B

Raymond Jang
Report Committee Chairman

WORKSHOP C

UTILIZATION REVIEW

Our workshop session dealt with the basic concepts of drug utilization review. The one concept is that of using data from any information system to determine what is or is not rational drug therapy or medical practice. If you will, we might call it systems practice, that is, using the right drug at the right time for the right patient. We know the definition of rational therapy. That's the one concept idea of drug utilization review. A second concept is the one in which we're talking about the monitoring of claims in third party programs, for signs of improper drug utilization. So, these are two different things and if you think about that for a while, I think you will agree that they are quite different. The requirements for input, the methods of storing, the method of retrieving and by whom and when and how are quite different.

A serious question arose within the group. This is the serious question of whether or not a drug claims processing system for payment to retailers can accomplish both of the above simultaneously. I will put that into context, if I may, a little bit. The first topic of the Conference has been how can claims processing in a monumental program covering the country, involving 200 million claims a year and up, be handled efficiently and the claims processed promptly. The second topic is what can you add to that system. If you add every one of the features that everyone would like to see in this system, you also raise this question: Rational drug utilization review, to be effective must employ a great amount of supporting data. You need diagnosis, primary, secondary, and, in some cases, tertiary; you need to know the medical complications as far as the patient is concerned; you need to know what laboratory tests have been run; whether or not there have been x-rays, what the long-term medical history of the patient is, if you're going to do proper, rational drug utilization review. Now, how do you get this? I don't think that Workshop C really felt that it could possibly be accomplished in an efficient, rapid, 14-day turnaround system of payment to pharmacists for dispensing prescriptions under a third party program.

One point brought into consideration is that maybe we should go back a step, and contemplate a system that would start in the physician's office or in his site of practice rather than in the pharmacy. I think that idea was alluded to in a previous presentation today. Another point was that there should be given serious consideration of regional or geographic differences in the medical requirements of various segments of our population. It is well recognized that there are differences by ethnic groups, there are regional differences in practice, in teaching, and training of physicians. This would have to be taken into consideration. A third point was raised, expressing concern about drug utilization review coming off a system such as we are contemplating here, as to timeliness of data. If drug utilization review information is going to mean anything it has to be timely. If the system is so large and so complicated that even with all the technology we can put to work there is a six-month or a year, or a 2-year or a 3-year delay in obtaining meaningful drug utilization review data, what have you accomplished? The information is woefully out of date. Timeliness, therefore, is a problem. This is mentioned by the previous speaker but it came up in our workshop a number of times. I don't think it can be dismissed lightly.

Another point raised is the question of confidentiality and invasion of privacy. Somehow this has to be resolved very early in the game to make sure the design takes into consideration how we can deal with a patient's name and identity and the physician's relationships without breaking confidentiality. I should think pharmacists would have to think very seriously about that in view of the code of ethics of APhA. For example, I know a marketing researcher we had to get special clearance, if you will, from the Judicial Board of APhA saying that it was permissible and not breaking the code of ethics for a pharmacist to allow us to examine prescription files so long as we did not take the patient's name as part of the information, nor the physician's name. That is something to think about. Now perhaps the Federal government is exempted from this, but what about the role of the pharmacist? Where is he? What does he do in view of the code of ethics?

Another major consideration at the present time is that a number of different interests currently are building different systems to accommodate drug claims processing for a variety of purposes. There's Title 19 in the Insurance field; you have social security and others; all in force. In addition to that you have allied interests. You have the computer people, you have research people, you have wholesalers. All are developing some sort of automated system for data handling and in various segments of called pharmacy and pharmaceutical distribution. A major point that was made was made yesterday, and it was reiterated numerous times in our workshop sessions, where is the threshhold at which point all these diverse activities which are working now, are being expanded and are getting more entrenched, we can say, "Stop, go back to the beginning. Undo all this and start all over again." A question was posed, "What kind of catalyst will have to come into this picture, to say we're going to do it one uniform way, going to consolidate all into one."

The sixth point revolved around the concern expressed by the group on numerous occasions, that as far as drug utilization is concerned, the system should not be built emphasizing the catching of the cheater. We heard a good deal about that as far as drug utilization is concerned. Cheating exists, yes; however, a very minor part of all medical practice is in that area. Shouldn't the system be organized the other way? A system which allows an ethical, dedicated, honest practitioner to practice without hindrance, and one which regulates only those who fall outside that particular environment. It seems that the emphasis has been going the other way, that is, one hundred percent inspection of everybody in the system.

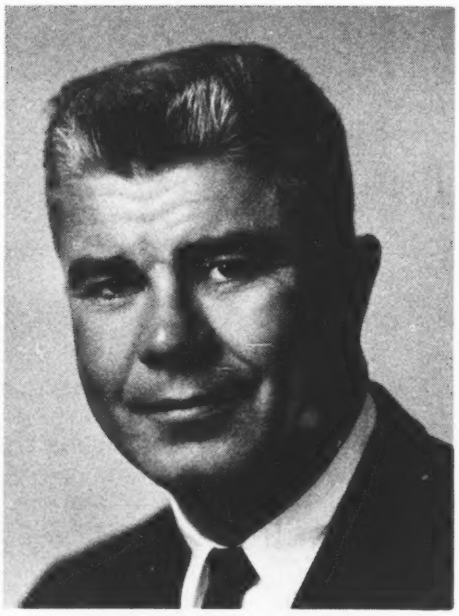
On number 7 point, there is no consensus in the group. We felt we thought we should report a negative finding as to whether or not there should be drug utilization review other than to monitor third party claims for apparent misuse. We all can see that in the third party program there is a need to know where improper utilization is occurring. But to go beyond that is another matter. Who is going to develop the kind of information that is needed for this rational therapy situation? Should it be the government? Should it be private industry? Should it be a combination of the two? Sometimes it should be government entirely; others feel no, it shouldn't be the government at all; should be in the hands of private citizens. Others feel a combination of the two. I feel compelled to comment on drug utilization review for market research. Where will this be available? Government sources or private sources? Still manufacturers are going to need market data for production purposes. Planning of production and planning of research are essential and this planning must be timely. The Food and Drug Administration needs data as quickly as any of our clients. The goal of a drug utilization system, I think is this: the goal of the drug utilization review system should be to reduce the number of transaction units rather than just trying to cope with the existing volume. We talk about the 500 million transactions but have we really gone into this from the point of view of whether we can really cut down effectively the number of transactions that have to be monitored, thereby simplifying and probably cutting down the cost of the system.

There was another question. Peer review was discussed at length in my group. In other words, who shall be responsible for the peer review of the data which would come forth from a wide scale data processing system for drugs. Who is going to do it? Some people say you let the data speak for itself. That's one object; just set it up and let the computer do it. You can program a computer to tell you when something is not normal and by how much and when, but does the computer know the basis of a diagnosis which must include the history of the patient. So, who is going to do the peer review. What criteria will be put on drug utilization? How reasonable can that be? Should not the medical practitioner be involved in the design of a system for drug utilization review? Is it fair or reasonable in any large scale drug utilization review situation to work behind the doctor's back or should we seek his active participation in such a review system?

The last very serious question was raised about the feasibility, the practical feasibility, of a terminal in each and every one of say 50,000 pharmacies. That includes one in the Point Barrows, Alaska. Is it reasonable to do that? Or, perhaps only concentrating on the stores that have the volume, again how do you determine this, or are there other ways of doing this? Probably one of the biggest paper-handling jobs in this country is the Internal Revenue Service. We pay our taxes, but each of us doesn't have a terminal in our home to submit our tax data to the Federal Government. We are asked to walk down the street a little bit to the nearest Internal Revenue Service office. Interestingly, there are 800 Social Security offices in the United States; and there could be 1,000 without much trouble and that represents one social security office for every 50 pharmacies; maybe terminals in 800 Social Security Administration offices would do batch processing for the 50 stores in the area. That might be a better way to look at it. Chairman, that summarizes Workshop C.

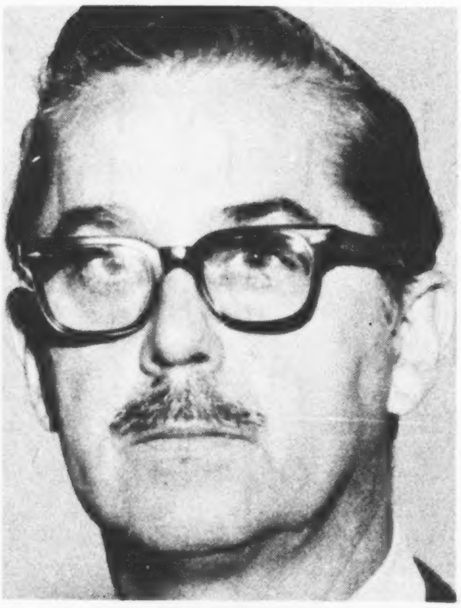
Ray A. Gosselin, Reporter
Committee Members: Charles S. Reeves
Arthur S. Waite
Ben D. Ward

Ray A. Gosselin
Workshop C



C. Earl Kennemer
Workshop D

Claude V. Paoloni
Chairman, Pharmacists Panel



Jeff D. Whitehead
Report Committee Chairman

WORKSHOP D

EMERGENCY PREPAREDNESS

We had the very difficult problem of dealing with the Emergency Preparedness aspect of this meeting. People do not like to think about something happening to everything that they now have. Most of us end up not thinking about it. Each of us in our own way prepares for an emergency. We are all worried about too little, too late. When it applies to us and it becomes too overwhelming, we have the problem of sometimes just quit thinking about it. And the problem we face is to convince people to think about it just a little bit.

But, whatever disaster planning, whether it's for personal disaster, community disaster, or national disaster, it must be part of a built-in system. It cannot be something that we are going to do right now in a hurry when the hurricane is coming up, the flood crest is coming down the river, or the tornado season is upon us. It must be like an iron fire escape on the outside of the building. It must be there. It must be like our liability insurance. It must be paid up and in effect. It must be like our seat belts, it must be straped, buckled, and in place. I'd like to read our statement:

"Emergency health preparedness must plan for both outpatient and inpatient needs of projected disaster victims. Output data needs require a total drug information system designed to monitor all drug-dispensing channels. Planners for this information system must design maximum flexibility and compatibility with other health and social information systems, as yet undeveloped.

"1. Needed data output is normal stock levels of essential survival drugs and supplies throughout the distribution system. Only a portion of the total inventory and a sample of the wholesale and retail drug stores will be monitored. The purpose is to assess the availability of these items under various disaster conditions and to identify critical shortage areas. The users of these data would be planners for disaster health preparedness, the Federal, local and state people.

"2. Needed data input is levels of medical supplies available postdisaster, that is categories, amounts, and locations. The purpose would be to provide command control with data on probable availability of medical stocks so as to allocate scarce resources among claimants in the postdisaster period. Special needs are redundancy of computer facilities, programming, and back-up alternate assignments of tasks to assure postattack survival of this computer capability. Users would be emergency managers of essential health survival items.

"3. Needed data input is specific amounts of drugs and supplies being used for the care and treatment of those injuries and illnesses expected to be serious problems in the postdisaster environment. The purpose would be a prior planning for National Medical Stockpiles and would be used by planners for Disaster Health Preparedness.

"4. The needs are a compatible interface of system hardware with other parts of larger health information systems. This is based on the assumption that other systems will be developed and the drug information system should be designed so as to have compatible hardware interface with other systems such as a poison control system. Data bank of poison information should be maintained at a single location and responsive call-up from this bank could be obtained by accessibility code from regional facilities. This single bank would contain information on all possible hazardous material and would be supplemental to a system which contains data on drug overdosage and adverse reactions. The users would be the Poison Control Centers.

"5. Input needs are hospitalization costs for victims of poisoning. A part of our program was discussion of the present control system. A patient who has ingested a poison or an overdose of an unknown drug may present the emergency medical care system with a miniature disaster because of the lack of knowledge of the ingested material or the most appropriate treatment. There is a need for the hospitalization costs of this particular disease category especially to justify funding of preventive programs. The user would be the Food and Drug Administration.

"6. Needs are recall capability of hazardous pharmaceutical products. Lot and batch number prescription items should be input into the patients' record so that recall drugs can be rapidly located, not only throughout the distribution system but at the point of use.

"7. The last is an observation: The workshop noted that an objective of present inventory control is to reduce certain stock levels to an economic minimum by use of computer controls. If emergency medical supplies are among those items so reduced at all distribution levels serious problems could result in the event of a major national disaster. Present discussions with industry have revealed their positive desire to avoid such a dilemma and should be so noted."

C. Earl Kennemer, Reporter

Committee Members: Juanita P. Horton
Paul K. Kaetzel
Edgar A. Parsons, Ph.D.
Henry L. Verhulst
A. Arthur Lowenthal
Jamshed A. Modi
David Ray
Duane Steinshouer

PHARMACISTS PANEL - VIEWPOINTS

It has been very heartening to me as a practicing pharmacist to witness a metamorphosis from what on the day before yesterday was extreme frustration concerning the magnitude of this great project we are considering, and what seems to be coming out today. It appears that there is a lot of overlapping between our committees, but everything is coming out the same. This is fine.

There are several items which need to be included in the development of a computerized information system which would relieve the pharmacist of some routine duties, thereby freeing time which is needed to be devoted to professional functions. The consensus of the Pharmacist's Committee upon which I served agrees upon the following addition to a program of E.D.P. such as we have been discussing here. They fall into two categories, the administrative and the professional.

First, I will discuss the administrative considerations. For third party and related records, we established a first priority to a means of validating patient eligibility. This would include the identification of any deductible feature of a particular program and also involve the standardizing of a single means of processing all third party claims. Second priority concerns developing a means of performing the total pricing operation for each claim. I realize that this might get bloody before it's all over with, but this is one of the most time-consuming routines that we, as pharmacists, are exposed to. Quite often we have to stop everything and figure out how much to charge for, say 36 tablets of an item which we received in a container of 250 units and cost may be $8.67. If we could do something to resolve the time involved in unwinding this sort of thing, it would afford a much needed relief. A third priority involves performing an inventory control. Included are the following items: the control of legend drugs, BNDD drugs, dated items, surgical aids and appliances, over-the-counter drugs, and disaster preparedness supplies. A fourth priority was assigned to the preparation and summarization of payrolls.

The following items would also be desirable but are of somewhat less importance, when consideration is given to the system loading potential, than are the foregoing: provide information relative to accounts payable and receivable and also on cash receipts; departmentalized sales data; tax summaries; profit and loss statements inclusive of a daily log of this item; personnel records and insurance programs; and product recall or withdrawal.

The second major category of information which we considered involved the professional application of an automated system to provide a quick access to individual drug indications, side effects, dose schedules, contraindications, special precautionary statements, and the interaction potential with other drugs, foods, beverages, disease and other entities. Access to this kind of information for every drug with which we are involved would facilitate the monitoring of drug therapy through electronic data process access to patient profiles which are inclusive of a positive means of identification, such as, the name and address of the patient, his next of kin or dependents, date of birth, known allergies, hypersensitivities, or chronic disease, the current diagnosis of his health state, laboratory reports which are standardized for the nation, and a medication history for both prescription and OTC medication. We need at the same time a system of communication from the pharmacy to the prescribing physician; a means of alerting the physician to any possible interaction contingency or other questions which might come to our attention.

A good deal of reservation apparently exists on the part of some concerning whether the pharmacists, as they now exist, are capable of performing this monitoring function. I would, without qualification, emphasize here that if the pharmacists could receive this information in the order and in the manner I have just described to you, there is no question that there is a very significant area in which they can perform efficiently in monitoring drug interactions and therapeutic misadventures. This is, after all, the reason for the existence of pharmacy. I have been told by some of you present here that the pharmacist doesn't have the competence to perform in this area. At the same time, I have also been encouraged by the recognition given by people like Dr. Jacobus, who yesterday emphasized that whatever we plan here we should not minimize the potential for this program to upgrade the quality of medical services available to the people of this nation. Since the title of this conference is "Computer-Based Information Systems in the Practice of Pharmacy", I trust it not to be presumptuous to assume that Dr. Jacobus intended this to be reference to the state of underdevelopment in which pharmacy practice currently exists, and the attending benefits which would be made available through a restructuring of this important paramedical service.

In the June 17th issue of the New England Journal of Medicine, Kenneth L. Melmon authored an article involving the incidence of drug toxicity and interaction which exists in the hospitals of America today. Melmon reports that from 18 to 30% of all hospitalized patients have a drug reaction, and the length of their hospitalization is about doubled as a result. He also states that 3 to 5% of all admissions to hospitals are primarily for a drug reaction, and that 30% of this group have a second reaction while hospitalized. It is reported that one-seventh of all hospital days is devoted to the care of drug toxicity. The total cost of these avoidable influences has been estimated to be three billion dollars a year. Considering that this estimation is restricted to hospitalized patients, then it would probably not be an exaggeration to say that we could project a total cost of, at least, five billion dollars a year that is the result of an inadequate system to function in the area of drug monitoring. Keep in mind also that here we are not giving any consideration to humane influences.

I have been involved in a patient medication monitoring project in my pharmacy for about four years, and I would say to you that the intellectual challenge which has been facilitated through this approach to our work is needed by the pharmacists of this nation and is needed desperately. The resulting bountiful fruits, both to the public, the physician, and also the pharmacist, will exceed all imagination. The attitudes which are prevalent right now, exemplified by the fact that there are those who apparently seriously believe that the pharmacist cannot perform the function of prescription monitoring, are the result of the influences which have come to bear upon pharmacy in the time period since World War II. In this era we have all been blessed, and I use "blessed" reservedly, with the great evolution of new drugs which has descended upon us and has caused the pharmacist to lose this traditional function which has always been through the years, until this recent interval, the reason for our being...our concern for the patients we serve and the mixtures of medications they receive. Nothing could have intervened to avoid the resulting trauma which has been inflicted upon pharmacy through this exposure to too many drugs too soon. Time was the missing and irreplaceable ingredient...the factor which exacted the toll of haste. The inclusion of an access to patient medication profiles in any program of computerization of third party claims processing probably offers the quickest available means of a rehabilitation of the practice of pharmacy to its former functional status.

The potential of E.D.P. systems to provide information which could upgrade the practice of pharmacy, and thereby improve the quality of health services available in this nation, appears to be boundless. As a concession to system loading problems we submit the following items for consideration of inclusion in this program:

1. In the area of drug utilization, we need to establish a means of confirming to the physician and the pharmacist whether the patient's prescription has been filled.

2. The problems associated with prescription refilling can be very time consuming. A method of determining the eligible refills promptly and of establishing the status of the number of refills of any prescription at any given time can materially assist in this problem.

3. There is a need for building into the system a method for detecting prescription forgery. A possible solution to this was alluded to when the Drug Data Panel report suggested that the physician, instead of giving prescriptions to patients, should feed this information into a computer center from which the pharmacist can draw it out. This appears to be an excellent approach to the problem of counterfeit prescriptions.

4. We also need an automated means of detecting the patient who frequently obtains the same medication from multiple sources whether it be for fraud or for drug abuse.

Jeff D. Whitehead, Reporter

Panel Members: Claude U. Paoloni
John A. Dawson

2. ROUND TABLE

ROUND-TABLE

Discussion of Selected Issues
Based on Workshop Committee Reports

Moderator: Donald T. Rucker, Ph.D.

Panelists: Riley J. Jeansonne
Ray A. Gosselin, D.Sc.
Jeff D. Whitehead
C. Earl Kennemer, D.D.S.
Paul D. Olejar

Olejar: That concludes the reports. At this time we will go to a form of discussion we will call the Round Table. The purpose of the Round Table is to summarize major points, pose some of the major questions, and trends. I will now turn the microphone over to Don Rucker, who is a recognized leader in drug studies in relation to health insurance programs. Dr. Rucker.

Rucker: Would the Round Table members care to come forward so we can solve all the problems of the world -- I think our work is cut out for us. Would you all like to come up here and we can pass the mike back and forth. While you are assembling, I will ask Ray Jang for a bit of clarification because I would like to let that comment rest if I understand his point correctly. Now for the questions.

I.

Should a third party system also provide for information on drug utilization and various patient care functions?

Rucker: As you can tell from the excellent summaries of the five individuals who have just appeared before you, we have some major issues. Let me start the ball rolling by asking the members of our Round Table to comment on what I regard as perhaps the most serious dichotomy that has appeared. I don't know if we can solve it this morning, but further amplification is surely in order. And that's the issue of whether a third party program should be confined largely or primarily to the task of processing and paying claims, or should that additional dimension -- the function of utilization review, the provision of education for the profession, and the enhancement of patient care -- should this indeed be a major or primary goal of any third party program and the concomitant development of any comprehensive, drug-record system? Would you pass the mike back and forth as you address yourself to this question. Is this really a dichotomy? Can we develop an organizational structure to permit both functions to be carried out, or are we going to have to live with doing one job or the other for quite a while in the future? Riley, would you like to start?

Jeansonne: I certainly believe that all of the items that Don mentioned are necessary. I don't think that all are necessary simply to process a claim form. I think that the data needed to develop other information can be gathered at the time the initial data is selected and submitted. I think, that more than an elementary or primary approach at this time, with the technology we have and the networks we have, if you want to call them that, would be somewhat of an impossible task to say nothing of the cost/benefits. A lot of these things can be done. Some form of utilization review can be done. A lot of the commercial aspects that we've heard about -- payroll, accounts receivable, etc. -- can be done -- as a by-product of the claims process -- but not as an immediate part of the claims processing system.

Gosselin: I see it clearly as a dichotomy. I don't think we can develop by 1990 one system that will do both of the jobs we are talking about. The pressures of claims processing and taking care of the economic side of it is going to be paramount, I think, in any large-scale program. So drug claims are going to take priority, as I would see it, just out of sheer necessity. You can add to the claims processing certain additional information which will certainly be of help, but to develop a broad network for a monitoring of the entire medical services field -- and that's what we are really talking about -- that will work and be reasonable and can accomplish what we do, it seems to me is clearly a second problem, a second system, both of which would have to be developed differently.

Whitehead: My personal knowledge of data processing really doesn't permit me to arrive at a truly valid evaluation of the capacity in this respect. However, the business of drug monitoring is needed badly now and we have a situation that exists in the nation whereby we have a large group of pharmacists who have been involved with simply mechanical operations of counting and pouring and typing. We are presented with dual need. One is for a means that must be devised so that this type of pharmacist can help to upgrade the total health care process. The other is for our schools -- our pharmacy schools -- to adjust their curricula to emphasize education in this direction. Somehow the planning of the system must address these needs.

Kennemer: There is no doubt in my mind that of the things that were discussed here today, many of them are quite desirable and recommendations of this conference, like most others, will read like a long list. To prevent those who might be the implementers -- our legislators, our administrators in government who might be providing the dollars -- from thinking and choosing as we might on a buffet, we must build a solid foundation for each of these aims, and a time and a phase, then they won't tend to pick and choose and then say that they have implemented the recommendations of this conference. Because, if you do not have this solid foundation, you are faced by these people who only have an interest because it is a political thing to do, and they've got a lot of "why don't you do this." and "what if you do this?" I think personal data in a system will bug us from the start and we might as well be ready for it. You can't talk to physicians about such a system without their being ready to talk about malpractice suits. We must be able to face this question of this personal information data squarely. We've got to be ready to fight.

Olejar: I would like to say that the question of whether you need two systems, or whether one can ride on top of the other, is a question that does not need to be settled at this time. The real question to settle -- do we need both types of systems, or both types of operations?

II.

Should we begin the network by placing terminals first in physician's offices rather than in pharmacies?

Rucker: There is another issue that has been raised in Panel B, Panel C, and by Mr. Whitehead, that I didn't expect to have as much attention here as seemed to arise. That is the question, should society consider the possibility of the development of terminals first in physician's offices rather than in pharmacy locations? Now this objective will,of course, result in a more comprehensive, sophisticated systems requirement, and I think that panel members might address themselves to the general question. Is such a development a desirable or indeed a necessary additional step in the over-all pharmacy information records system? How do you regard this?

Jeansonne: I think that this is a loaded question in a sense. I think it certainly is desirable to gather as much information as possible at the original site. Just to give you a few facts about the Medicare program -- at this particular point in time, approximately 50% of the physicians will not sign an assignment which means that the government does not pay them directly, and the patient must pay the doctor. The other case is one in which the patient's bill is paid by the government, to the physician. I would love to see a system where the physician would originate the order. It would cut down on a lot of abuse. The first thought in planning a Medicare drug program was to originate the order for the data processing claims system in the physician's office. After considerable thought we decided to exclude the physicians, but to use the prescription which he wrote as the instrument or the original base for the processing of claims. I wish that we could say that we have the full cooperation of physicians. It seems that this is often true in a state program where physicians have a great deal of control on the regulations and rules under which they operate. When it comes to the Federal Medicare System, it is a different situation. When it comes to other third party or private plans I imagine that you might have even more difficulty though I'm not sure about that.

Gosselin: This is not really a difficult question for me to answer for this reason, because my answer has to be obvious from my answer to the first question. I do see two different systems needed. The first one, for claims processing -- I say no, I don't think we have to go back to the doctor's office for that. We can operate pretty well the way we are now. But the fundamental point is, to do the second part, the national rational therapy analysis, I don't think you can begin to even design that system without starting in the doctor's office. You just don't have the input that you would need to do the job. So for one you do and for the other you don't.

Whitehead: It is my impression that the name of the objective in our game should be to improve the quality of health care available to the public of this nation. As a pharmacist, I am very well aware of the immense depth of mixed drug therapy that is emerging now as more information is being made available concerning the action of one drug against another, or drug-disease influences and this sort of thing. And while I wouldn't argue that some terminal facilities in a doctor's office would not be desirable, I'm convinced to my own self that we could go further in improving the quality of health services in making a means available to the pharmacist to activate himself to a functional role. The physician has enough to do in his involvement with the patient of diagnosing and prescribing without also becoming encumbered with the constant consideration of this very broad field of drug interaction. For that reason, I don't think we should pass up the pharmacy as a terminal.

Kennemer: I just believe we should have a total information system and what ever hardware, software, or forms that we need to somehow get to the point where a patient has one record in one place that is accessible to any health professional who needs to perform a service for him and needs to know the information that is in there. How he gets it is immaterial if he can afford it.

Olejar: I have to agree with Ray Gosselin that if you are also going to do drug therapy analysis you had better not leave the physician out. And that's true whether you have one system or two.

III.

Should we incorporate other medical information with drug utilization data?

Rucker: I think the panel has now identified what I regard as the third issue that might be distilled from this meeting, namely, to what extent do we look at drug use data by itself, or, to what extent do we try to incorporate other medical information? This problem will be a continuing question, but are there any particular thoughts that you have? We'll start with Riley here as to how one might proceed. Do you think the most desirable approach should be to expand the data that is collected on the prescription form? Or should carriers take an alternative approach of trying to relate drug records to independently gathered medical-record information? Or, is this an issue that is so complex that we are not going to be able to do much in this area during the next several years except, of course, to continue to study and experiment? Is there any hope for expanding the data base by which we evaluate the nature of prescription services other than the basic information which is found on the prescription order form itself?

Jeansonne: As presently visualized, the claim data that has been suggested here approximates 70 characters of information. That's quite a lot. Seventy times a million prescriptions a day is 700 million bits of information that would have to be processed. While it is certainly desirable to expand this, I think it would be impolitic to do so at this time. Within our own shop at

Social Security there are means by which we can derive data from physician services and correlate these data with prescriptions at a later time. Of course, this would not be immediately beneficial, but for teaching needs and for teaching aids, for upgrading the practice of pharmacy and medicine, and perhaps the development of rational drug prescribing and rational drug use, we could do this after-the-fact. The period or time frame that I am talking about would certainly not exceed three or four months after-the-fact of prescribing, dispensing and billing.

Gosselin: A number of references were made during this conference about the analogy of the moon shot -- that we finally did get a man up there on the moon after ten years and had spent 24 billion dollars. But I don't think we should lose sight of the fact that we put seven men up in Mercury one at a time. The first three didn't even orbit -- they just went up briefly. Then we went on the Gemini for about six or seven years with two men and they didn't go anywhere except around the world a few hundred times. Then finally Apollo -- and it took a long time to do this. What we seem to be talking about here is, let's build Apollo first in this drug information system. I just don't know that can be done even with 24 billion dollars. I think, being in the business of sampling statistics, that we are missing an awfully good bet if we attempt to develop a census system of prescription claims and assume that we need a census to make evaluations of what is or is not good medical practice and what the medical services are. The Census Bureau itself, years ago, came to the conclusion that every ten years it had to count all the noses in the USA, but it didn't have to ask everybody in the country about many other things about their lives. They found that they could take a statistical sample, ask them about what was going on, and project from that to the nation and very accurately. And this is the way it is done in business; that's the way it is done in many other things. So to answer the question, I think this: Start off with what is obvious -- you need a census for claims purposes. Add to it what you can to make it work. Then develop sampling statistics to get at the other data -- that's the Mercury design in Gemini; add a little bit more and finally end up with Apollo.

Whitehead: I'm not positive that I understood Dr. Rucker's original direction but I think it was - from what sources do we obtain information; should it be extra information, should it be included on the prescription blank or where does it come from? Was this involved in the question? ... Well, I don't want to be repetitious. As a pharmacist, I cannot downplay the need for an access to the patient's medication profile for every patient. Norms are not going to save one individual's life. We may do surveys and come up with the fact that an apparently insignificant amount, say a 1% occurrence of a certain sort of drug toxicity exists in certain situations. But this is not going to do any good for the patient who happens to be the victim of this sort of situation. So with that in mind, I still contend that we need access to each individual patient's profile.

Kennemer: I agree with both of the two previous gentlemen, but I think there are two different things we are getting there -- one for the patient and one for the industry, that is, the health, medical, pharmaceutical and the whole professional community. There were two different things here. One we get by sampling -- yes, we do. And I yield to no one to say he has more faith in statistic size sampling than I do. I believe in it and this is the only economic way to get it. But I also believe it is wasteful to think of any other thing but the patient.

In our concern for averages we get into the problems. Our health education systems in our schools come up with a health educator saying "Johnny, you're A, you do B and you'll end up C". But will he?

Olejar: It seems to me that if we're talking about the immediate next two or three years we have no answers. If you're talking about 1980-85 perhaps some answers can be developed by a competent study of the alternatives open. And I would like to leave it to that group.

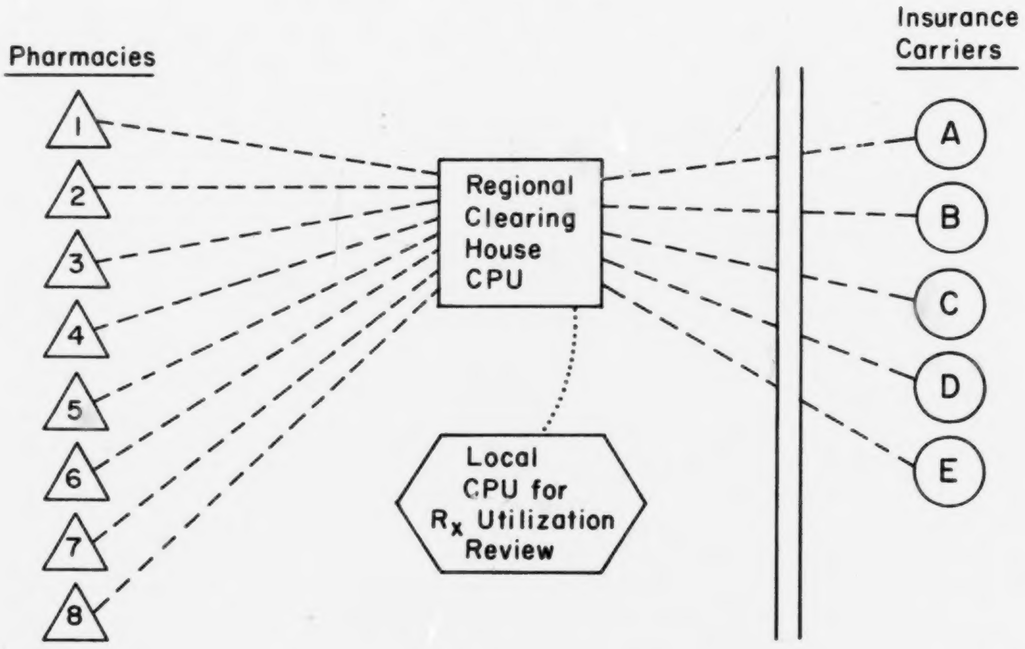
Schematic of Drug Information System

Rucker: May I call your attention to an obvious point which is often overlooked in efforts to relate drug records to other medical records. Any time you are faced with a deductible, such as the Part B deductible under Medicare, the program is likely to have less than complete records. An administrator can't relate prescription information to other medical data that is not readily available in the system. A carrier also has the same problem with respect to the exclusion of particular types of services. The program may cover drug services in a comprehensive way, but if certain types of medical procedures are excluded from coverage, this restriction has much the same effect as a deductible in compiling complete patient health-care records.

Now undoubtedly there are additional questions that might be discussed, but if you will let me take about two minutes I would like to put a small diagram on the board. Perhaps the panel and maybe even members from the audience would like to comment on this schematic. (See diagram on following page.) I have outlined a potential, simplistic solution for resolving the first problem that we raised earlier in the panel discussion, that is, the question concerning how extensive can the claim processing mechanism be, particularly from the point of view of any third party program. Drug claim processing and utilization review need not be incompatible objectives if we are willing to think in terms of a clearing house based upon terminals and regional computers.

You can conceive of these units on the left as being pharmacies who participate in a particular region. Then you will have a regional CPU (Central Processing Unit) and all of the messages for the third party claims go automatically into the system. Ultimately, the credit sales of the pharmacist can be sent also to this same CPU for particular handling. Later on one could conceive of instances

Terminal/Computer Drug Record System


Pharmacies
1
2
3
4
5
6
7
8
Regional Clearing House CPU
Local CPU for Rx Utilization Review
Insurance Carriers
A
B
C
D
E

when cash sales data would also flow into this CPU. (We may get to that purpose in a moment.) But at this time, we have now defined very quickly the concept of the clearing house with the purpose of getting claims information into the system through the technique of source data automation. Thus, when drug data comes into the computer, you have prescription records in machine-readable language.

The next step requires that the CPU in the region transmit prescription claim data, still in machine-readable language to the CPU of the carrier. The carrier's computer, or computers, of course, may be located anywhere that the carrier chooses to locate them. This development means that the number of carriers that the system can accommodate may increase or decrease as the needs for carriers or administrators change. It also means that we can have compatibility here between private programs and government programs because the clearing house solves the problem to the left of the double line by getting drug records into the system efficiently and effectively and hopefully with a great deal of accuracy.

Now the reason I've introduced this diagram is not so much to lay out the particular configuration of the system but to try and focus our attention on the question of whether claim processing and drug utilization review are actually incompatible. One may assume that third parties are going to give primary attention, at least during the early stages of program coverage, to the processing of claims, and, of course, that they will exercise their normal responsibility with respect to the evaluations of claims in terms of abuse and fraud. The question then becomes -- what do we do about the general concept of improving the quality of patient care through the technique of utilization review. What can society do to help the profession educate itself about better quality of care both with respect to professional practice and in the medical schools as well.

Regional Review Level

I'm going to suggest today that the function of drug utilization review be operated at the regional level and that this be divorced from carrier operations. One of the advantages of this realignment of responsibilities is that the claim processing function would no longer be encumbered by requirements of handling and evaluating data for the purpose of utilization review. This is an elementary version of the schematic, but I do think that it does have some potential for resolving our mutual problems. (I am also aware of some of the limitations, and there are some I don't know of, I'm sure.) Nevertheless, if this clearing house proposal does have operational validity, maybe the net advantages merit some comment by the panel gathered here today. The issue is an exceedingly important one, namely, what is the purpose of third party drug coverage and can we indeed accommodate two basic functions simultaneously without necessarily encumbering the effective functioning of either? Ray?

Gosselin: I think Don's diagram, which we should have really included in our summary, and I'll see to it that it is because it is an excellent one, comes back to the problem we've talked about. If this is going to work at all, you've got to go back behind #1, #2, #3, and #4. This is the fundamental issue we're talking about. If we start at #1, we're talking about pharmacy output and what do they have available. What I'm speaking of is not in the diagram. The average pharmacy in this country has betwee four and five thousand people who are dealing with it, so you have all that patient input. In addition, you have your MD's and we find, for example, that pharmacies now have as many as 150 to 200 different physicians' prescriptions in their files. Now the question is - how are you going to get the input from them about what they've diagnosed, etc. to accomplish utilizatio review?

The other thing I want to mention here is something that shouldn be lost, and that is the mobility of the American public. We found in recent studies that 38% of all of the prescriptions filled in America are traveling, and that is quite astounding. If you take any given metropolitan area and look at the core of the city and the suburbs, 38% of the prescriptions are traveling one way or the other at all times and that varies tremendously by diagnosis, by therapy, by doctor type. I'm not trying to shoot the idea down; I'm just pointing out another complication of how to keep the records together.

Rucker: We have about two more minutes -- any other members of the panel wish to take a crack at this question? Riley?

Jeansonne: I agree with Don in that I want to get the rest of you to relate to all carriers. Certainly the carriers are paid for processing pharmacy services, but they also are paid for physician services, etc. I think the physician will be less prone to let third parties release data if they all give the data directly, rather than to the pharmacist. For that reason it would be best to go the way of pharmacy first. I find that it would be most difficult to ask -- impossible to get -- the diagnosis on a physician's prescription. He doesn't mind putting it on a claim that he is making from a third party, but for him to put a diagnosis or primary/diagnosis on a prescription would be almost impossible. He would leave himself wide open to legal implications. Usually this person is being treated symptomatically. The physician may treat and may change the dosage or change the drug within a few days. The patient may be hospitalized or what have you. And some smart lawyer might pick up on things like this and try to prove a case in court and embarrass the doctor. They know this as well as we do. And I feel certain that while they do not mind a third party which has limits of confidentiality imposed upon them, they would almost unanimously not give this to pharmacists as part of the prescription data. They would rather go through the intermediaries with respect to the diagnosis step.

Rucker: Well, if you don't mind, gentlemen, I'll terminate this portion of our discussion. Dean Hager needs a little time for the Conference Summary Session...Harry, do you want to raise a quick question?...

(Question from floor)

The question concerns the ability of the pharmacist to maintain patient profiles, and I assume that would be essential. The clearing house diagram is a simplified version, and we could, I'm sure, talk about it for many more hours, but Dean Hager needs to have the floor.

III. CONFERENCE SUMMARY

1. RESUME

George P. Hager, Ph.D.

Mr. Olejar referred to an epilogue at this stage. I hope that what we now do will actually be a prologue. Pharmacist Clinician Jeff Whitehead referred to a metamorphosis in the thinking and attitudes of this Conference as it has proceeded. And, I think he is perfectly right. I hope that you have sensed this also. I think that initially there was a strong tendency toward an inductive type of reasoning. At first, we tended to emphasize the trees and, to some extent, lose sight of the forest. But, as we interacted we became more aware of other trees, and we changed to a deductive approach in our reasoning.

One of the virtues of this Conference, in my judgment, has been a general disinclination toward an excessive preoccupation with detail. Details are important, but they certainly can be very serious impediments to progress along a very general line which must be, at least initially, somewhat more idealistic. However, the expertise of the pharmacist with regard to the rational, safe, and effective use of drugs is not idealistic. It is very real. Students complete five years of intensive study of drugs in this school, as in other schools of pharmacy, in order to qualify as pharmacists. Moreover, the demand for the pharmacist's expert knowledge of drugs and their proper use in the care of individual patients is also very real and not merely the idealistic dream of pharmaceutical educators. Drug information systems and a communication network enabling pharmacists to draw upon those systems to expand greatly their application of relevant knowledge of drugs in the care of individuals may be somewhat idealistic at this point in time, but it is an idea that must be put into practice for the benefit of individual patients. A communication network of this kind would be to the pharmacist's intellect as a microscope is to the eye. Many physicians would also benefit from direct access to the overall system and would take advantage of the system. I contend, however, that the pharmacist is an essential component of the cybernetic loop of a system that would benefit all physicians and all patients throughout the broad and varied health care complex.

I think we should ask ourselves at this prologue stage of this Conference, "Where are we now?" Certainly we are two and one-half days older. I think we are also two and one-half days wiser because we have benefited from the different viewpoints that have been expressed by others who are looking at a common problem but from different points of view. This kind of an interdisciplinary dialogue is most beneficial. I think the really pertinent question is, however, "Where do we go from here?" I would like to assure all of you, as I have a number who have asked specifically, that the proceedings of this Conference will be distributed as promptly as possible. The manuscripts that have been prepared by our speakers and the written reports of the workshops will greatly expedite the preparation of the proceedings and we are most grateful for them. However, I hope you will agree that this Conference should not terminate with the distribution of the proceedings. I hope you will agree that we should now take concerted action that will lead directly to a chain of events that will have been triggered by this Conference. We should now strive to discern the common thread in the thinking of the people who have participated and to proceed from that in formulation of the next step. It was a great privilege to attend the planning sessions, to sit in on the Conferences, to discuss individually in the halls many of the things that we are concerned with here. I have presumed, therefore, to make a rough draft of what, at least in my judgment, appeared to be a common thread leading into a next concerted step. This has already been distributed to you. I hope that you will modify it in every appropriate way so that the ultimate resolution will represent our concensus with regard to "Where we should go from here."

....

The proposed resolution, after discussion and slight amendment, was adopted by a voice vote at the concluding session of the Conference.

WORKSHOP OBJECTIVES

Tutorial and deliberative workshops were organized during the Conference as follows:

A. Third Party Payments and Related Records

> This workshop dealt with a nature of a proposed computer-based information system to handle record-keeping for third party payments, accounts receivable, and related topics; identify required "hard-core" data elements.

B. Computer-Based Systems for Drug Data

> Case histories were presented of innovative approaches to gathering and using information on indications, contraindications, drug/drug interactions, and adverse effects of drugs. Participants identified hard-core data elements from the standpoint of pharmacy practices as a substantive contribution to the total system requirements.

C. Drug Utilization Review

> This workshop dealt with the concept of drug utilization review as a component of a total computer-based information system designed primarily to serve third party payment programs, both as a means of enhancing health care and as a means of facilitating surveillance and control of abuses.

D. EDP Support for Emergency Preparedness

> The usefulness of EDP information system in handling such problems as preparedness for disasters was explored; and tentative data requirements were suggested.

A panel of registered pharmacists also was organized to monitor the workshop proceedings and make an independent evaluative report to the Conference reflecting the interests of practicing community pharmacists.

Workshop moderators selected panel members to assist them; and a number of papers read by the panelists significantly augmented the tutorial contributions.

Four ad hoc committees were selected, one for each workshop, to summarize the discussions and formulate such recommendations as seemed to be desirable to be considered by the Conference as a whole.

RECOMMENDATIONS

A. Third Party Programs

1. A prescription data collection and processing system has several unique features:
    - an enormous volume in a dynamic flow
    - a small dollar value per transaction
    - the need for a significant amount of data from each transaction

    These features result in the following requirements:
    - extremely low cost for data collections
    - accuracy of input
    - fast claims processing
    - complete data, which results in responsible management

2. The ends of responsible management of a prescription claims system are, from a fiscal point of view:
    - prompt, correct payment
    - immediate awareness of trends for program control

    From a professional point of view, responsible management derives:
    - the ability to develop profiles
    - family record system
    - drug abuse data

3. By-products of the claims processing system are:
    - drug recalls
    - drug vendors
    - inventory control

Data Requirements

Number of Characters	
9	Physician Identification
9	Patient Identification
6	Vendor Identification
9	Drug Identification
6	Transaction Number
2	Refill Indication
6	Date Prescription is Filled
3	Quantity of Drug Dispensed
4	Charge for the Prescription
3	Number of Days Supply of Drug
3	Payer

It is suggested that the Patient Identification be the SSA number in that it be both unique and permanent. The final number should be chosen in a joint effort with the AMA.

B. DRUG DATA SYSTEMS

The pharmacist can contribute most correctly to health care service if he directs his efforts to advising the physician and patient on safe and effective drug therapy. For this purpose a properly designed information system would be highly desirable. A computer-based system should be considered.

The system should be so designed as to give the pharmacist information while the patient is with him rather than after the prescription has been filled.

The system should help support these functions of the pharmacist:

Direct
(60% of his time)

(Things he does in interaction with the patient or physician)

- *Dispensing of medications - 54%
- *Rx usage control - 6%
- *OTC drug usage control (advising patient on whether or not a medication is indicated by his condition) - 6%
- *Drug Monitoring (comparing current orders with previous to look up allergies and interactions) - 6%
- *Health information (advising where information can be obtained on drug abuse and poison control) - 6%

Indirect
(40% of his time)

- *Accounts receivable (third party)
- *Accounts payable
- *Inventory control
- Merchandising
- Personnel management
- *Financial management
- Civic service

*Potential Areas for Computer Contribution.

Description of a Fully Developed System

- . MD's office enters Rx into regionally organized data bank
- . Patient goes to pharmacy of choice
- . RPh queries data bank for new drug orders and current drug history (including allergies, drug interactions, etc.)
- . If no history, dispense Rx
- . If problems, consult MD
- . When Rx is OK, have the computer terminal prepare the label and initiate payment process
- . Drug order is filled
- . Pharmacist advises patient about Rx

Information Necessary for System Implementation

a. Situational Data

(Relating to A Specific Transaction)

- MD and Entry Operator
- Patient Identification (individual and family)
- Patient's Date of Birth, Sex
- Third Party Identification
- Diagnosis
- Drug Rx
- Drug Rx Order
  - Directions
  - Quantity
  - Dosage
  - Form
  - Strength
  - Date
- Drug Rx Fulfillment
  - Date
  - RPh
  - Technician
  - Lot Number
  - Brand Dispensed
  - Refill Authorization
  - Price
  - Quantity
  - Action Indicators (Patient Consultations, MD Consultations)
- Drug History
- Idiosyncracies
- Pharmacy Identification

b. Resource Data

- Drug Names and Codes (ASHP-DPIF)
- Adverse Reactions and Drug Interaction Data
- Cautions, Warnings
- Restrictions, Legal, Investigational, Controlled Substances Act

Questions to Ponder

Will this system reduce cost from present practice?
Who will pay for the difference, if any?
Confidentiality of information?

C. UTILIZATION REVIEW

There is recognition that there are really two types of drug utilization review.

a) Using data to determine what is, or is not, rational drug therapeutic practice. That is, using the right drug for the right patient at the right time.
b) The monitoring of claims in a third party program per se for apparent improper utilization.

There is a serious question as to whether or not a drug claims processing or payment system can accomplish both of the above.

a) Rational therapy utilization review in order to be effective must employ a large amount of supporting data -- primary and secondary diagnosis, complications, laboratory tests, x-ray, long-term medical history, etc.
b) Regional or geographic differences in medical treatments or practices must be recognized. Disease incidence in ethnic groups, etc., must be taken into consideration.

Concern was voiced regarding the timeliness of data for utilization review, because of the enormity of any system to handle the payment of drug claims. Extended delays in obtaining such data would defeat the purposes of drug utilization review for both government and private industry.

Serious questions were posed regarding confidentiality and invasion of privacy.

At the present time we are building up a number of different systems to accommodate drug claims processing. At some point in time this approach will be completely unworkable in being able to handle the volume. It is felt that the critical point will probably be reached whenever a Federal program outlines a common approach.

The point was made that to overemphasize a drug utilization procedure to identify "cheaters" alone will not be in the best interest of long-range systems development.

On the matter of the drug information system there was no concensus, with the thinking ranging all the way from a federally implemented and operated program to a simple claims payment system employing nonterminal methods. A great deal of discussion dealt with the notion that perhaps two systems should be implemented: (1) an efficient claims processing system and (2) a sophisticated service utilization review system.

Drug utilization review data for marketing research purposes by both industry and government agencies may be available from either industry or governmental sources; however, a concrete decision on this matter has not been reached.

The goal of a drug utilization system should be to reduce the number of transaction units rather than just react to the volumes projected on current experience.

The question was raised as to who will establish the criteria by which peer review will be conducted?

Should not the medical practitioner be involved in the design of a drug information system of the magnitude discussed at this seminar?

D. EMERGENCY PREPAREDNESS

Emergency health preparedness must plan for both outpatient and inpatient needs of projected disaster victims. Output data needs require a total drug information system designed to monitor all drug-dispensing channels. Planners for this information system must design maximum flexibility and compatibility with other health and social information systems, as yet undeveloped.

a) Needed Data Input: Normal stock levels of essential survival drugs and supplies throughout the distribution system.
Purpose: To assess the availability of these items under various disaster conditions and to identify critical shortage areas.
Users: Planners for Disaster Health Preparedness.

b) Needed Data Input: Levels of medical supplies available post-disaster, i.e. categories, amounts and locations.
Purposes: To provide command-control with data on probable availability of medical stocks so as to allocate scarce resources among claimants in the post-disaster period. Special needs are redundancy of computer facilities, programming, and back-up alternate assignments of tasks to assure post attack survival of this computer capability.
Users: Emergency Managers of Essential Health Survival Items.

c) Needed Data Input: Specific amounts of drugs and supplies being used for the care and treatment of those injuries and illnesses expected to be serious problems in the post-disaster environment.
Purpose: A prior planning for National Disaster Medical Stockpiles.
Users: Planners for Disaster Health Preparedness.

d) Needs: Compatible interface of system hardware with other parts of larger Health Information System.
Discussion: That Drug Information System be designed so as to have compatible hardware interface with Poison Control System. Data bank of poison information should be maintained at a single location and responsive call-up from bank could be obtained by accessibility code from regional facilities. This single bank would contain information on all possible hazardous material and would be supplemental to a system which contains data on drug overdoses and adverse reactions.
Users: Poison Control System.

e) Needs: Hospitalization costs for victims of poisoning.
Discussion: Additional support of preventive activities can be justified using this cost data.
Users: Poison Control System.

f) Needs: Recall capability of hazardous pharmaceutical products.
Discussion: Lot and batch number of prescription items should be input into the patient's record so that recalled drugs can be rapidly located not only throughout the distribution system but at the point of use.
Users: Food and Drug Administration.

g) Observation: The workshop noted that an objective of present inventory control is to reduce certain stock levels to an economic minimum by use of computer control. If emergency medical supplies are among those items so reduced at all distribution levels, serious problems could result in the event of a major disaster. Present discussions with industry have revealed their positive desire to avoid such a dilemma and should be so noted.

E. PHARMACISTS' VIEWPOINT

A concensus of those items needed to be included in the development of a computer-based system which would relieve the pharmacist of some routine duties thereby freeing time which is needed to be devoted to professional functions. These fall into two categories, administrative and professional.

Administrative Application

First Priority: (a) A means of validating patient eligibility. (establish deductible features of various programs). (b) A standardized method of processing all third party claims.

Second Priority: Develop a means of performing the total pricing functions for each claim.

Third Priority: Perform an inventory control inclusive of the following: Legend drugs, BNDD drugs, dated items, surgical aids and appliances, O.T.C. drugs, disaster preparedness supplies.

Fourth Priority: Prepare and summarize payrolls.

The following items would also be desirable, but are of somewhat less importance than the above: Provide information to accounts payable and receivable; cash receipts; departmentalize sales; tax summaries; profit and loss statement (daily log); personnel records; insurance programs; product recall or withdrawal.

Professional Application

Provide quick access to individual drug indications, side effects, dose schedules, contraindications, special precautionary statements; interaction potential with:

a) Other drugs
b) Foods
c) Beverages
d) Disease
e) Other entities

Facilitate the monitoring of drug therapy through access to a patient profile inclusive of the following:

1) Name and address
2) Next of kin or dependent
3) Date of birth
4) Known allergies or hypersensitivities
5) Diagnosis
6) Laboratory reports
7) Medications history (both Rx and O.T.C.)

Develop a means of communicating from the pharmacy to the prescribing physician to alert the physician to possible interaction contingencies.

First priority has been assigned to the above requirement. The following information would also enhance the quality of health service available to patients:

Drug Utilization

1. Establish a means of confirming (to the physician and the pharmacist) that the patient's prescription has been filled (or not filled).
2. Problems associated with prescription refills are very time consuming. A method to determine promptly the number of refills, if any, and the status of the number of refills of any prescription at any given time can materially assist in this task.
3. Build in a means of detecting prescription forgeries.
4. Devise an automated means of detecting the patient who is frequently obtaining the same medication.

RESOLUTION

WHEREAS, a pharmaceutical communications network connected to all licensed pharmacies is needed for a number of purposes among which are some that alone might well justify the network; and

WHEREAS, a modular pharmaceutical communications network would be applicable, seriatim in order of priority, to a number of purposes that cannot be served as efficiently otherwise and which, in appropriate combinations, would fully justify the network; and

WHEREAS, the network would provide a universal ready access to existing and emerging drug information systems, that in themselves, would require redundant network communications systems for their efficient application to the needs of a large and varied patient population; and

WHEREAS, the time is rapidly approaching when traditional manual procedures for some of the purposes that could be served by the network will be completely inadequate and grossly inefficient, e.g., administration of third party payments for prescribed medications;

BE IT RESOLVED, that an interdisciplinary task force be established to study the feasibility of a pharmaceutical communications network that will operate initially on a state-wide or regional basis for a pilot study or demonstration of modular components designed to fulfill the multiple purposes of a network that will lead to a more rational and more economical use of drugs in patient care; and

BE IT FURTHER RESOLVED, that the Federal Government provide the necessary funds for a full-time staff for the task force and for stipends and expenses of the task force members who will study the feasibility of a pilot study network and submit a proposal to the appropriate Federal agency for the support required for its implementation.

IV. SELECTED PAPERS

1. FEDERAL AGENCY SYSTEMS

INFORMATION SYSTEM SUPPORT FOR THE CANCER CHEMOTHERAPY PROGRAM

Barbara R. Murray*

The Chemotherapy program, one of the four major segments of the National Cancer Institute at the National Institutes of Health, leads collaborative efforts among other NIH and NCI scientists, other government agencies, pharmaceutical industries, research institutes, and universities to find new and better antitumor drugs and to use them more effectively. Such a drug development program in all its complex aspects requires the continued coordination and utilization of the resources of the Federal government in collaboration with private segments of biomedical research endeavors throughout the country and indeed the entire world. The Program utilizes results of clinical trials carried out in such places as Japan and Africa, and we are setting up two overseas liaison offices in order to get such information more quickly.

Only within the past several years have investigators been able to report that the goal of drug therapy to reach tumor cells and selectively destroy them has been reached for the rapidly growing tumors.

One can readily see that such a drug research and development program as that maintained by Cancer Chemotherapy has many reporting requirements for various levels of scientists and managers. Today I shall describe briefly three of them and Dr. Greenfield will demonstrate the Drug Data Sheet tomorrow.

Each of the reports to be described serves a different purpose and provides information to a different type of user. Each of the systems is complete, has been used in an operating mode for several years, and probably most importantly to this group, has been designed and developed with the cooperation and assistance of a multidisciplinary group including physicians, pharmacists, and data processing personnel.

(A slide was shown saying "The purpose of our system is to bring it to the user.")

Management and Cost Report

1. The simplest report to be described is essentially a management and cost report. The Chemotherapy program provides free many Commercial Drugs, IND drugs and special formulations of commercial drugs to Cooperative Groups who are caring for cancer patients. A monthly report of shipments to physicians is issued primarily to aid the Cooperative Groups (who participate in clinical trials) and the

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* Chief, Program Analysis, National Cancer Institute, National Institutes of Health, DHEW, Bethesda, Maryland.

Extramural Program (who fund the groups) in the preparation of budgets. In addition, the Chemotherapy Program needs to know on a continuing basis the amount of funds to allocate for the purchase of drugs.

Secondly, usage information enables us to predict through simple regression techniques, the potential drug costs for the next fiscal year. These amount to a sizeable portion of our budget. This report therefore, is essentially a management tool to account for costs expended, to ascertain whether investigators receiving large amounts of drugs have complied with the requirements, to submit data, and to estimate the amount of drug required to carry out a protocol. In addition, Investigational New Drugs considered to be approaching the commercial stage are also carried on this report as an aid in forecasting.

Plotting of results and retrieval by drug name, investigator name, cooperative group, etc., occur routinely to provide information on demand and aid in determining trends. Further, with restricted budgets during the last several years, Cooperative Groups were assigned ceilings and the percentage of ceiling reached by each group for each time period was calculated and reported. This proved an excellent monitoring tool. Sample copies of these reports, as well as a graph, are available for your inspection.

Drug Data Sheet

2. The second system, the Drug Data Sheet, was designed to provide information on Investigational New Drugs and Commercial Drugs for quite a different audience, that is, the nursing staff and the new Clinical Associates who report each July first. Here the information provided is that about the characteristics of the drugs, their stability, formulation, doses, side effects, etc. Sufficient data is given for each drug to supply the requirements for informed consent, but the sheets have not been used for this purpose and do not replace the physician.

The Clinical Center uses many experimental drugs for which manufacturers' information is not available. Further, the pertinent information concerning drug forms, dosage, route, complications, toxicity, and other pharmacological parameters, changes as experience with the drug increases. In order to provide the information needed to detect patient responses and insure accurate drug administration, PRA developed a system which allows rapid response to changes in any of the abovementioned parameters and also allows the availability of this information directly from a time-shared terminal. This was an ideal test for CPS (the Conversational Programming System) as the data is entirely free text in nature and more easily input and updated via a terminal-oriented systems facility. (As a parenthetical note: Had the WYLBUR system been available then, the Drug Data Sheet might have been implemented in quite a different form.)

In any case, the user of the Drug Data Sheet logs onto the computer and through conversational interaction with the system indicates the nature of the information desired. The program asks the user to supply a protocol number, NSC number, or IND number. It then prints the pertinent data for the specified drug or for all the drugs corresponding to the given chemotherapy protocol. The most usual application is to enter the patient name, chart number, and protocol number. The computer searches its list of protocols to obtain the address keys of all the drugs used in that protocol and then prints out the abstracts for each drug on chart-size paper. Identifying information is typed on the bottom of the sheet including the patient name, number, protocol, date of printing, and the date the abstract was last revised. You will see a demonstration of this system tomorrow, but sample abstracts are available today.

The system can also provide bibliographic information on a given drug, abstract of a specific drug, or a list of the NSC numbers of all drugs for a given protocol or all drugs used in the system. In addition the user can add, delete and update drug abstracts from the terminal in conversational mode. An inexperienced operator can learn the system in relatively short time with little assistance from professional personnel. We allow users to comment on the format of the system or the information in the abstract, request new drugs, point out problems, or make suggestions they may have noted in their use of the terminal. We do not permit them to clobber the data base.

The major difficulty in the system is the slow operating speed of the terminal which can type only 15 characters per second. With newer equipment, such as a CRT terminal with hard copy attachment, one could print the abstract at 120 characters per second (or faster) and then produce hard copy automatically with an electrostatic copying attachment. This would obviate the need to keep track of page location and index to the top of the page, which, as you will observe, occupies much of the time that the user spends at the terminal.

Initially we planned to provide a personalized summary for each patient-on-protocol's chart. However, the slow speed of the 2741 terminal led to physicians' preference for a bound book of abstracts which are updated periodically.

Automated Monitoring System

3. The last system to be mentioned today is one developed jointly with the Baltimore Cancer Research Center, part of the Chemotherapy program, and the Health Research group.

The system was reported at the Cancer Meetings in April, 1970, and has been submitted to a pharmacy journal under the title of "Automated Monitoring of Drug Therapy". Dr. Greenfield and I have some copies of the medication form in which each of a patient's drugs is marked at the time of drug administration. Drug and patient identification are typed on the card using a Selectric typewriter with an OCR (Optical Character Recognition) typeball, and the data is read weekly by optical scanning. Both weekly and cumulative summaries of drugs administered are produced. The medication card fulfills all the requirements of drug ordering, administration, and recording in addition to providing machine-readable data for computer input. Sample outputs may also be seen today.

This system, which has been in operation for over two years, eliminates the transcription operations usually associated with preparation of reports for computers and provides a data pool for clinical studies, analyzing drug effects, toxicity and drug interactions. BCRC is the only part of our program that has had ward-based pharmacists, who perform many of the functions listed in the pamphlet that Mr. Danziger distributed. This is probably one of the reasons this form has worked so well. Also the program includes an up-to-date drug dictionary and fairly extensive editing facilities, both of which help.

In conclusion, I have described three drug-related systems operating at the National Cancer Institute during the past two to three years. Each system performs a function supportive to the mission of the Cancer Chemotherapy program.

If anyone is interested in more information, please feel free to contact Dr. Greenfield or me.

FOOD AND DRUG ADMINISTRATION

BUREAU OF DRUGS INFORMATION SYSTEMS

Alan Gelberg*

I. The Regulatory Responsibilities of FDA(Bureau of Drugs) are in two major areas:

  A. Premarketing Area

    1. Investigational New Drugs (INDs)

    2. New Drug Applications (NDAs)

    3. Final Printed Labels (FPLs)

  B. Marketing Area

    1. Assay (Analytical Methodology)

    2. Adverse Reactions and Drug Experiences

    3. Medical Advertising

    4. Clinical Investigators and Facilities

II. Areas of Standardization are required for computer processing:

  A. The National Drug Code is a 9-digit number

    1. First three digits refer to manufacturer

    2. Fourth through seventh digits refer to product

    3. Last two digits refer to package size

  B. Chemical Abstracts Registry Numbers are used for specific chemical compounds

  C. The FDA Dictionary of Standardized Terminology is being compiled

III. Existing satellite computerized systems that are now operational in FDA are as follows.

  A. RAPID (IND and NDA scientific file). This is being connected through a contract with Informatics, Inc. to a Mark IV file format

  B. NDC (National Drug Code)

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C. DESI (Drug Efficacy Study Implementation) is being organized by a contract with Automated Systems, Inc. (Averbach)

D. Medical Advertising Alerting System

E. Adverse Reactions (Form 1609)

F. Clinical Investigators

G. Chemical Substructure Search

H. Drug (Establishment) Registry File

I. Over-the-counter Drugs

J. Literature Alerts (CA Condensates, CBAC, MEDLARS, Ringdoc, Vetdoc, Pestdoc)

IV. FDA spin-offs to be available to public within one year include:

A. FDA Dictionary (Development copies available now)

B. NDC tape/hard copy (presently available; tape from NTIS and Directory from GPO).

C. DESI tape/hard copy (initial form of the "Compendia"): tape depending on demand.

V. FDA spin-offs to be made available to public within two years:

A. Data from NCTR (National Center for Toxicological Research)

B. Assay Methods (U.S.P., AOAC, Bioavailability, etc.)

C. Tape/microfiche of the Total Inventory System

D. Microfilm set of drug labels (if demand exists)

VI. Conclusion - FDA is proceeding with the forementioned projects to meet Agency and Bureau needs. The spin-offs will be formatted for ease of distribution through the NTIS (National Technical Information System) or the GPO (Government Printing Office). Purchasers will have the option of using the spin-offs in any manner they choose without restriction.

INTRODUCTION TO THE NATIONAL CLEARINGHOUSE AND ITS AUTOMATED SYSTEM

Henry L. Verhulst*

The increase in the number and variety of products that began to enter the American household after World War II and the corresponding proliferation of such incidents as the accidental poisoning or suspected poisoning of children, created mounting concern among pediatric and other medical groups, public health authorities, and other responsible persons, about accidental poisonings. This concern set in motion a series of events which has resulted today in the daily twenty-four hour operations of some 580 autonomous Poison Control Centers in the major population areas across the country, among whom information about household products and medicines that are toxic (and nontoxic) is coordinated by a National Clearinghouse. This Clearinghouse has operated as part of the Public Health Service since it was formed, and since July 1, 1968, has been the responsibility of the Food and Drug Administration.

By 1952, incidents involving possible poisoning of children from various products used in the home, including medicines, were being encountered by physicians in fifty-one percent of reported childhood accidents. Obviously, the practicing physician cannot be familiar with the composition of all household products; yet, knowledge of the ingredients is necessary for the proper treatment of an ingestion case.

Because of this knowledge gap and because there were hundreds of thousands of such ingestions annually, the Illinois Chapter of the American Academy of Pediatrics initiated a pilot project called the "Poison Control Center," in Chicago in November of 1953. The number of other poison control groups that subsequently were organized with the same goals as the Chicago Center can be considered a tribute to the latter's success. The centers soon found, however, that they were duplicating each other's work in compiling information and that the information gathered by one was not finding distribution to all. Moreover, information about poisoning experiences was fragmented. It became apparent that some coordination of poison control center activities was necessary.

In November, 1956, at a meeting of the American Public Health Association, a committee on which several groups were represented recommended that a National Clearinghouse be established to provide sources of reliable data and a meaningful case reporting system for poison control centers. The APhA presented this recommendation to the Public Health Service of the Department of Health, Education, and Welfare. As a result, the Surgeon General designated the National Clearinghouse for Poison Control Centers as an official activity of the Public Health Service and it was assigned to Public Health Service's Accident Prevention Program. Although the National Clearinghouse for Poison Control

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*Director, Division of Hazardous Substances and Poison Control, Bureau of Product Safety, Food and Drug Administration.

Centers is the name by which it became best known, it is now officially designated as the Division of Hazardous Substances and Poison Control, Bureau of Product Safety of the Food and Drug Administration.

580 Centers Now

Since 1957, approximately 580 Poison Control Centers have been established in the United States. Except for the few in Government hospitals, these centers are not under Federal control. They are largely autonomous organizations developed by local hospital or paramedical groups in cooperation with the State Health Departments. Although every hospital should be prepared to treat the emergency aspects of poisoning cases, only a comparatively small number of poison control centers are needed to accumulate the specialized experience and reference material to provide information services. With few exceptions, financial support of the poison control center comes from the hospital in which it resides. Although poison control centers were originally established as a service to physicians, they have evolved to a point where today almost 75 percent of the calls they receive are from the lay public. The structure of a poison control center varies considerably from one area to another. The majority, however, are usually located in emergency rooms of large community hospitals. Their documentary resources consist of a file of 5 by 8-inch cards provided by the National Clearinghouse that lists information on commercial household products and other substances, along with references that usually include textbooks on poisoning, plant toxicity, pharmacology, and occupational medicine. (See Attachment 1.) Most centers maintain a list of consultant experts who are called when unusual poisonings occur. The occupation of the professional person taking calls at the center also may vary. Often, it is a nurse or a pharmacist with several years of experience, with a physician on call.

Clearinghouse Support

The National Clearinghouse supports poison control centers by providing data to them on the ingredients, toxicity, symptoms and findings, and recommended treatment involving the more common household products and medicines children are likely to ingest. This material is periodically supplemented to cover changes in formulations and new products that enter the market. The information is gathered from a number of sources. Many manufacturers voluntarily submit formulations and toxicity data on new products. Others respond to Clearinghouse questionnaires concerning new products discovered from the case reporting system and from reviews of commercial and scientific journals. The information is researched thoroughly and evaluated by the staff. Then it is submitted to four consultants for review before distribution.

The poison control centers submit case reports voluntarily to the Clearinghouse. The information contained on these reports is obtained by center personnel whenever they treat a poison case or respond to a telephone call requesting information on a potential poisoning. Over 115,000 case reports were submitted by the centers to the Clearinghouse in 1969 and again in 1970. The Clearinghouse reviews and codes each report which is then key punched and entered into the systems data bank which resides on magnetic tape. From the data bank statistical reports, reflecting data gathered on a national basis, are published. This information provides a variety of program materials useful in the Division's operation. The age and sex of the victim and the circumstances of the incident form a basis for prevention and education programs. The amount of substance ingested, compared with the symptoms of the patient and days of hospitalization required, provide important clinical data on toxicity of a particular product.

Reports are produced and distributed to each state which reflects all cases reported by each center within the state and a summary report of the total activity for the state. Also, each poison control center receives reports which are produced from cases reported from that center. From this same data base monthly reports are generated for cumulative cases reported. These reports relate to: (1) the most frequently ingested products, (2) products most frequently causing hospitalization. These two reporting methods generate reports by age groups as follows: under five years, over four years, and unknown ages. Periodically selected data are extracted from the data bank to generate reports which are used to answer special requests received by the Clearinghouse.

Use of Computers

A toxicology data bank on magnetic tape is now being compiled that will include all the information on the 5 by 8-inch index cards in the poison control centers. In the future all the information in the Clearinghouse files will be added, along with pertinent information from textbooks and other sources. A pilot study has been conducted in which the Boston Poison Control Center and the New Orleans Poison Control Center participated with the National Clearinghouse.

The computer facilities being utilized for this study were those at the National Institutes of Health. The Food and Drug Administration did not possess the necessary equipment and expertise to accomplish this at the time the study was undertaken. This is no longer the case and the plans are now underway which will result in the transfer of this study to the Food and Drug Administration.

For the pilot study data base approximately two thousand products were used. It was felt that this number would be adequate to test the feasibility of an on-line toxicology system. The fact that inquiries would be made to this limited data base for products which were not present was recognized.

Information that can be supplied almost instantly by this system following a query includes the name of the product, type of product, ingredients, toxicity level, symptoms, treatment, manufacturer's name and address, source of information, and the emergency room data reported for that product.

The study has not proven to be any faster than the previous manual retrieval system, but the new study does alleviate the possibility of human error through the misfiling of cards, or the incorrect spelling of some product names. The computer is equipped to pick up these incorrect spellings, inform the center that additional information is needed and if necessary conduct a search of its term dictionary file to determine the correct spelling of this product. A second plus for a computer-based system is its ability to store large volumes of information on trade name products. A third plus for an on-line computer is the fast and easy manner in which the data bank is updated when contrasted with the slow cumbersome procedure inherent in the manual system which requires that all changes to the data bank be copied and mailed to each center. The following problems exist within the present manual system:

1. Because each center is responsible for maintaining its own separate file, the situation arises in which all centers do not have the same information. This is brought about due to lost, stolen, mislaid, or misfiled cards.

2. The present 5 by 8-inch card which contains product information does not contain any information related to human experience concerning product toxicity. Space is not available on the card to include this information and to go to a second card (a two-card product information concept) would only duplicate and compound the existing problems.

Results of Pilot Study

One objective of the pilot study was to prove that the problems in the manual system discussed above could be eliminated with an on-line system. This has been accomplished as described below:

1. With an on-line system each center will have new product information as soon as it is added to the Clearinghouse data base. This will eliminate the 4-6 months delay presently required by the manual system.

2. By virtue of an on-line system, this should increase their ability to answer questions. The poison control centers will eventually have access to the complete data base maintained at the Clearinghouse.

3. An on-line system will provide a uniform data base to all centers and will preclude problems engendered by lost, mislaid, and misfiled cards.

4. With an on-line system the centers will have human experience information on product toxicity as part of the base provided by the Clearinghouse.

Although the pilot study should definitely be considered a success there were some criticisms. However, we feel that the criticisms, which are valid, were directed almost entirely at problems which were the result of the hardware facilities utilized. More sophisticated facilities could have been used had the resources been available at the time the study was undertaken.

As mentioned in the previous section, the pilot study proved that on-line system would eliminate the problems existing in the present manual system.

The 2741 terminal was too slow an instrument for our needs. Although it printed a hard copy, characteristics were dropped. On closer examination we find that this can be inimical to a study of this nature. To drop, during transmission, a digit which relates to volume could obviously change entirely the meaning of the information received as result of an inquiry. Example: 95 mg. sent from data base, 5 mg. received at the center's terminal. Naturally this is intolerable and must be eliminated.

Summary

The material produced for Poison Control Centers by the National Clearinghouse for Poison Control Centers is placed on a 5 by 8-inch card in a standard format:

Trade name of product
Manufacturer and address
Toxicity
Symptomatology
Treatment
Source of Information

Four problems have become evident since the system was introduced: 1. cards are misfiled; 2. cards are removed from the file and not replaced; 3. updating and revising results in a 3 to 4 month delay; 4. the name of the product is often misspelled, hence not found. To alleviate these problem areas, we designed an on-line retrieval system. The products were identified by a six-digit number assigned alphabetically. Remember in Poison Control we are dealing with all household products including drugs. This number was then used as a basis for developing a program. The material is stored on a magnetic tape using free text and the format on our cards. It can be recalled by query in the trade name. No dictionary is needed.

We have two innovations which we are very pleased with: 1. we have incorporated phonetic spellings which will recall products with similarly spelled names, and 2. we have developed the system so statistical data on symptoms of previous cases will be incorporated into the information base at regular intervals. The user is therefore aware of the type and frequency of injuries, if any, occurring in previous ingestions.

We have been utilizing the system in two centers since mid-1970 with good success. The information was sent via an IBM 2741 terminal device. The major complaint was the lack of speed in delivery and a degree of garble. This did supply a hard copy. We are now converting to a cathode ray tube. The system developed by Mr. Rottman has solved the problem of speed and corrected several bugs in the system. We expect to have four units in operation by this fall. The delivery system is practicable, our program now is to move forward in enlarging the data base as rapidly as possible and increase the number of terminals to geographic areas to get maximum utilization of the program for the centers in that area.

Name: Acetaminophen Type of Product: Antipyretic, analgesic
(N-Acetyl-p-aminophenol; 4-Hydroxyacetanilid; Paracetamol;
p-acetamidophenol; p-acetylaminophenol; p-acetaminophenol)

DESCRIPTION:

Acetaminophen is believed to be the active metabolite of acetanilid and phenacetin. It is probably directly responsible for the analgetic and antipyretic effects of these two drugs.

TOXICITY:

Acetaminophen does not cause significant methemoglobinemia and probably does not destroy red blood cells, but otherwise its acute toxicity would resemble that of acetanilid or phenacetin. It has oral LD50 values from 630 to 1020 mg/kg in mice. In humans, after ingestion of 1 gram, the peak plasma concentration occurs in 2 to 3 hours, and little or none remains after 8 hours. It is mainly excreted as conjugated p-aminophenol by the kidneys.

SYMTPOMS AND FINDINGS:

Based on animal and human toxicity of acetaminophen, acetanilid, and phenacetin, ingestion of toxic doses would cause nausea, vomiting, dizziness, sweating, feeble pulse, slow respiration, CNS depression, stupor, coma. This may be preceded, in some cases, by CNS stimulation including excitement and delirium. Terminal asphyxial convulsions may occur. Acetaminophen has not been reported to cause acid-base balance disturbances or hypoprothrombinemia. Possible renal damage.

TREATMENT:

Give milk or activated charcoal to delay absorption. If large amount ingested, induce emesis or perform gastric lavage. Maintain respiration. Symptomatic and supportive (OVER)

National Clearinghouse for Poison Control Centers, DHEW-PHS 12/67 3

(ATTACHMENT 1)

COMMENTS ON THE INFORMATION SYSTEM CONCEPT

Paul de Haen*

Definitions

I suggest that the following distinctions be made on information systems concerned with drug usage by physicians and handling of drugs in the retail pharmacy and hospitals. These two systems should preferably be kept apart, so that there is no confusion.

Drug Surveillance Systems

These cover primarily the movement of drugs as it pertains to manufacturers, drug wholesalers, hospital pharmacies, community pharmacies, and the relationship of such movement of drugs with third party government groups that pay for the cost of drugs.

Drug Information Systems

These cover primarily the information pertaining to chemistry, manufacture, pharmacologic action and therapeutic use of drugs as described in the biomedical literature.

Packaging of Drugs

I recommend that consideration to given to suggest to manufacturers that they develop a unit packaging of drugs which permits the pharmacist to dispense an original package prepared by the manufacturer, instead of having to repackage from a container supplied by the manufacturer for dispensing purposes. Manufacturers are spending a great deal of effort to cut down the cost of packaging drugs. This effort is vitiated by the pharmacist having to laboriously count out the number of units of a drug to be dispensed and put these in a dispensing container.

If this system, which is used in most European countries, South America and Japan, could be developed it would save a great deal of time and effort on the part of the pharmacist and reduce prescription costs.

A similar recommendation was also made in an editorial by Dr. Edward G. Feldmann, in the August, 1971 issue of the Journal of Pharmaceutical Sciences.

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*President, Paul de Haen, Inc.

Barbara R. Murray

Margaret K. Park

Henry L. Verhulst

David R. Work

POINTS TO CONSIDER IN A DRUG DATA SYSTEM

Margaret K. Park*

I. Standardization - There is a need for file compatibility for information sharing.

   A. Local Standardization - within one organization.
   B. Regional Standardization - more than one organization.
   C. National Standardization - U.S. as a whole rising from Federal regulations (example: Mark IV).

II. Data element is a discreet unit of information and should be defined in smallest terms of information to utilize or in terms of only one function in the system.

III. Characteristics of Standards

   A. Definition of a drug.
   B. What constitutes active ingredients in comparison to inactive.
   C. Vocabulary for adverse reactions.
   D. Constitution of level of affects.
   E. Set of standards for drug efficacy.
   F. Bibliographic sources to find where original information was found.

IV. Two Types of Data

   A. Keys to file (check codes) should be no larger than is really needed to represent information content.
   B. Display Data - does not have inherent checking ability, that "key" does.

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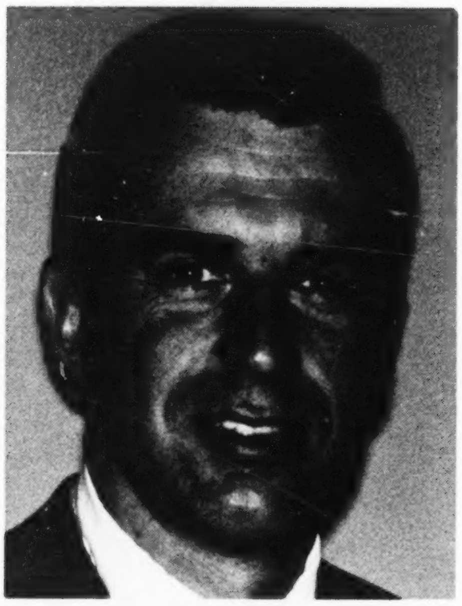
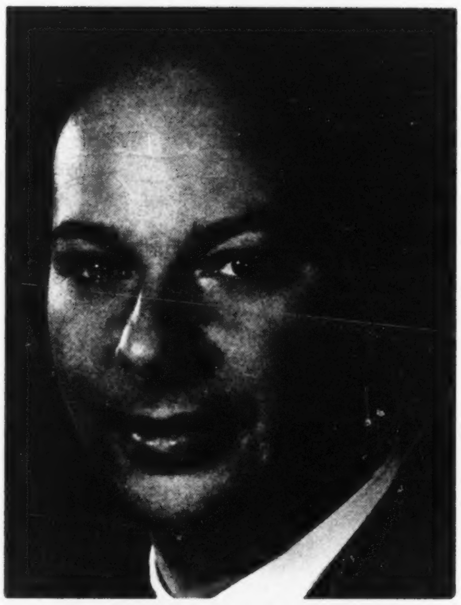


Frank Y. Yarborough



Michael Ripsman

Henry M. Kissman

Juanita P. Horton

TRIPS: THERAPEUTIC Rx INFORMATION AND PACKAGING SYSTEM

Michael Ripsman, L. Pharm.*

In the present method of prescription-filling, each practitioner has developed routines and techniques with which he is comfortable, and a mental library of useful information which he automatically consults before filling any prescription.

Government and Pharmacy Board regulations have contributed to some standardization of procedures, and the large retail chain organizations have imposed a certain discipline of techniques.

But, in the main, the techniques of prescription-filling depend on the habits and preferences of the individual pharmacist, and are intuitive in nature.

The use of information for, and from, the prescription-filling process is cursory.

The growth of Government and other third-party prescription plans has put heavy strain on this artisanal system, and threatens to make it unworkable.

The ever-increasing inventory of highly-potent drugs in the pharmacist's arsenal, requires a more extensive use of pharmaceutical and therapeutic information than has been the case in the past. Each of these drugs can become a poison if administered injudiciously, or in conjunction with other potent drugs. This situation has been outlined by a study at John's Hopkins Hospital which showed that in 1969, 17.4% of all patients admitted were suffering from drug reactions. Another 8% of all patients admitted, developed drug reactions while in the hospital.

No mention is made of the percentage of medication which had no beneficial effect due to careless choice of drug, multiple prescribing by varied physicians, or drug incompatibility. Nor is there any way of determining the percentage of drug reactions which do not become immediately apparent.

On the basis of the 8% figure for apparent drug reactions, it would not be unreasonable to estimate that upwards of 12% of drugs prescribed in the hospital have an adverse effect, or no beneficial effect at all. A serious study at the retail pharmacy level would most probably show less patient control and, consequently, higher abuse levels.

It should be pointed out that in a hospital filling 1,000 prescriptions daily, the above estimated abuse margin would result in 120 or more useless or noxious prescriptions dispensed daily.

The need for the systematic use of information, in the dispensing process, is clear.

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*President, Independent Retail Druggists Association, Inc., of Quebec, Montreal, Canada

Requirements for System

To maintain individual patient drug usage records containing:

I. Age, sex, medical and pathological information, drug reaction and allergy information, drug history information -

II. To maintain extensive pharmacological information about all drugs - side-effects, cautions, interactions, administration information, storage, etc. -

III. To provide this information to the dispensing pharmacist in a matter of a few seconds, so that he can utilize it in the prescription-filling environment -

IV. To mechanize some of the routine activities associated with prescription filling - typing of labels, preparation of bills and insurance claim forms, maintaining third-party accounts receivable -

V. To satisfy these requirements at a cost compatible with today's competitive pricing situation.

The requirements translate themselves into the following practical considerations:

a) to represent large amounts of technical data in a compact and significant manner -

b) to continuously update stored data in accordance with the latest information -

c) to develop methods of storing and sharing patient data on a regional level -

d) to develop methods of sharing pharmacological and patient data on a national level -

e) to make available to pharmacists relatively inexpensive hardware configurations and systems which will motivate them to use and to contribute to this network of shared information -

f) to develop a sufficiently flexible, modular system to meet varying regional needs, with options available as to the extent of the service desired.

The Therapeutic Rx Information and Packaging System, or "TRIPS", is an attempt to meet these requirements. The system has been developed to the stage where an in-house pilot project is required to determine cost and timing feasibility, and to debug the programs and system.

TRIPS

1. A method of representing, in a quantitative manner, pharmacological and patient information, of evaluating this quantified data, determining pharmacological relationships, and possible pharmacological-patient interactions, of automatically selecting pertinent information and displaying it in such a

manner as to suggest certain conclusions and precautions, within a few seconds, during the prescription-filling process.

2. An automated system which:
   prints Rx labels
   prints dispensing instructions AND
   prices prescription
   prepares Rx receipts
   OR, alternatively
   prepares insurance claim forms
   bills insurers.

3. The system is modular in structure. It is composed of three main sybsystems, each of which is a separate system in itself, capable of separate implementation. A manual packaging system is integrated with the computerized system.

A) Validation of prescription and patient data re: legal status pharmacological eligibility patient eligibility	B) Validation of insurance eligibility of patient and medication	C) Calculation of of retail COD price, preparation of receipt
Projections as to patient-pharmacological suitability	Processing and printing of claim form	Printout of requisite reports or records
Printing of fully-informative prescription labels	Maintenance of claim and billing records by means of an A/R-billing system	
Instructions as to dispensing		
Maintenance of patient records		
Maintenance of prescription records and files		

Within the three subsystems, programs and routines are modular in nature. Specific conditions will cause branching to a basic level of established programs and routines. Differing regional requirements, can be accommodated by modification of the branching conditions. Modification of the basic programs is also possible - but more costly.

TRIPS A-B-C = computerized system	+	TRIPS -M = manual packaging system	=	TRIPS A-B-C-M integrated dispensary system

Dispensaries would have the choice of the following options:

A, A-C, A-C-M

B, B-M

A-B, A-B-C, A-B-C-M

Specific Features

Data Entry

The keying of a code on an input terminal opens patient, insurance, and prescription files. File status is displayed on a cathode tube. Requisite sets of prescription, insurance, and patient data are then keyed.

The input data is edited, and errors are displayed.

Differing prescription and insurance situations, and varying status of files (including absence of a file) require a multiplicity of procedural routines. These have been integrated into one simple routine containing three optional subroutines.

The use of a graphic procedural chart, keyed to cathode tube displays, facilitates quick learning of entry procedures.

The routine is simple and automatic. Two days' practice should assure operator and/or pharmacist proficiency, providing that they were previously proficient with a typewriter keyboard.

Hold and Recall Facility

At any time during data entry or prescription processing, the working files can be dumped into a holding file by keying a two-digit code. A print-out of the work files is automatically produced.

This frees the computer for other processing while the operator or pharmacist is called away, while he gets further information, or while the pharmacist evaluates data which requires extensive consideration.

Keying the recall code reopens the master files, transfers the work files back to central code, and displays the assigned prescription file number and name of patient.

1. Prescription Number

As the input keying routine opens the work files, one file number is automatically assigned to both work files. This "assigned prescription file number" is read from a counter. It becomes the prescription identification number on the prescription label.

2. Determination of Legal Status and Right to Fill

Here, Canadian classifications and eligibility rules are used. American, or individual State, classifications and rules could be easily substituted.

FD = free drug (no prescription required)
PR = prescription required
CD = controlled drug
RC = reportable controlled drug
VN = verbal narcotic
SN = signature narcotic (reportable)

The legal status symbol is printed to the right of the least significant digit of the prescription identification number, on the label, e.g. 0020567PR 126500/SN.

The legal status classifications are code-keyed to eligibility rules which have been expressed quantitatively.

The right to fill is established. Alternatively, the prescription is rejected. On rejection a print-out, similar to an error print-out on edit, goes to the pharmacist.

3. Dosage Validation

Dosage is checked according to the age of the patient. There are three different sets of calculations and comparison procedures for three age categories:

Children under eight
Ages eight to seventeen
Adults

A-1 invalid dosage conditions give rise to the following display:

"Cautious Dosage
PDD
X units
Maximum Dosage
Y units".

4. Determination of Prescribed Drug Eligibility and Suitability for Patient

Criteria are numerous and varied, reactions and side-effects vary quantitatively as well as qualitatively. The TRIPS system works by classifying physiological and pathological data, and then representing these classifications quantitatively. Previous history of drug reaction and idiosyncrasy is listed.

The pharmacological and therapeutic actions of drugs and known side-effects are also represented quantitatively.

By means of calculation and comparison, possible undersirable drug-patient interaction is predicted and displayed.

A warning classification, the physiological or historical classification, and the name or class of the drug are displayed, e.g.

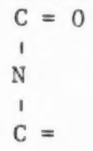
Caution	Idiosyncrasy	Barbiturates
Contraindicated	Cardiovascular Disease	Ethinyl Oestradiol
Contraindicated	Pregnancy	Prenylamine Lactate
Prohibited	Allergy	Meprobamate
Caution	Allergy	Sulfonamides
Prohibited	Phenothiazine Hypersensitivity	Pericyazine

The system is not exhaustive. The storage of drug information generically by therapeutic classification groups, enables "TRIPS" to store the major side-effects, precautions, and counter-indications of each group. Specific actions of a particular member of the group are stored when deemed important.

If comprehensive records are available for the patient, the system acts as a filter which should catch a good proportion of adverse reactions.

5. Validation of Prescribed Medication Against Other Medication Being Taken

Patient record is scanned to see if medication of the same therapeutic classification group is being taken concurrently. Then record is scanned for medications of therapeutic groups different from the prescribed medication, but which contain similar chemical nuclei or groupings, e.g., an antihistaminic phenothiazine and a neuroleptic phenothiazine

a cyclic 
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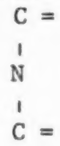
in a sedative, and a cyclic 
$\begin{array}{c} C = 0 \\ | \\ N \\ | \\ C = \end{array}$
in an anti-emetic.

Calculations are performed. Significant information is displayed. Then the therapeutic grouping of the prescribed medication is compared to the therapeutic groupings of all other medication being taken concurrently. Known interreactions and incompatibilities are displayed.

In the case of compound medications, each grouping is treated separately.

Finally, the prescribed drug itself is directly compared with other prescribed drugs for contraindications.

Information display is standardized into the following format:

Warning classification, interaction class, potential result, name of drug or group

Warning classifications: Caution
Contraindicated
Incompatible
Prohibited

Sample Displays

Caution	Duplication	Oversedation	Phenothiazine	Phenothiazine	0010624PR
Contraindicated	Potentiation	Hemorrhage	Phenylbutazone	Coumadin	0264719PR
Incompatible	Potentiation	Hypoglycemia	Tolbutamide	Sulfisoxazole	0315826PR
Prohibited	Unknown	Extreme Hypotension	Dextromethorphan	Tranylcypramine	0126748PR
Contraindicated	Potentiation	Respiratory Depression Cardiac Depression	Diazepam	Barbiturates	0342751RC
Prohibited	Unknown	Cardiac Arythmia	Guanethidine	Methylphenidate	1346876PR
Caution	Side-Effect	Extreme Drowsiness	OCNC	OCNC	0268883CD

6. Pharmacist Control and Options

The system is at all times under the control of the pharmacist. After validating procedures, the system displays relevant information. It will not proceed further unless an authorization code is keyed in.

The pharmacist evaluates the information presented to him. If he can make an immediate affirmative or negative decision, he keys in the proper code.

a) Authorization initiates insurance validation, patient record updating, prescription record storage, print-out of label, dispensing instructions, claim form and closing of files.

b) Rejection initiates flagging of work files, closing of master files, error print-out (see legal status).

c) If the pharmacist cannot make an immediate decision, he can avail himself of the hold facility.

d) He can then request a print-out of the prescription whose numbers are listed on the screen.

e) On recall, he can substitute another drug, to see if it would be more suitable. He can then call the doctor with a constructive suggestion.

In effect, the system does not replace the pharmacist. Rather, it provides him with information not readily available to him at present, within a few seconds, and allows him to take decisions on the basis of this information.

Further, it frees him from clerical routines.

7. Printing of Fully-Informative Prescription Labels

a) The Generation of "Add to Label" Instructions

The prescribed drug and dosage form information is obtained from the drug library and is automatically added to the doctor's instructions on the label.

Examples of "add to label" information:
i) storage and expiration information
ii) administration information (how, when, with what)
iii) possible side-effect information ("slight nausea may be encountered", "urine may turn green", "if dizziness occurs, call your doctor")
iv) precautions to be taken by patient ("do not drive a car while taking"), ("do not drink alcoholic beverages")
v) the maximum number of doses in any 24-hour period is always listed.

The small prescription label used at present does not give the patient sufficient information. Information is not always given verbally to the patient. If it is given, it is often forgotten or confused by the patient. The "TRIPS" system attempts to solve the problem by means of a large "Print-out label", and an inexpensive polyethylene bag fused to the prescription vial.

b) The pharmacist can key in additions to the label, by the use of a reserved entry code.

c) Instructions as to Dispensing
These list: assigned Rx number
code number(s) of product(s) to be used
quantity to be dispensed
particular container or insert,
instructions, compounding instructions.
name of patient

d) Repeat Prescription Option

Here, the prescription number and legal status symbol have been previously assigned.

Determination of Right to Refill

1. Legal status is read to determine whether prescription can be repeated.

If affirmative, number of repeats allowable is compared to number of repeats dispensed.

Minimum lapsed time between repeats is calculated, and compared to actual lapsed time since last filling.

The right to refill is established.

Restriction of repeat branches to previously-noted rejection routine.

2. Dosage validation, and determination of drug-patient eligibility and suitability routines are not necessary for repeat prescription.

3. The "add to label" routine is repeated, as it is less expensive to reprocess than to store this information on the prescription record.

4. The "validation of prescribed medication against other medication currently being taken" routine is repeated, because new drugs may have been prescribed for the patient since the last time this prescription was filled.

5. From this point on, repeat prescriptions are treated similarly to new prescriptions.

Insurance Processing

To enable the "TRIPS" system to process the unending variation in third-party-prescription-plan requirements, a set of universal requirement categories was abstracted from a representative sampling of these plans.

Each requirement category is represented as a variable in a single standard program. A relatively small insurance-plan file supplies the quantitative values for most of the variables. Keyed-in patient and prescription data supplies the values for the rest of the variables.

If the eligibility or payment rules of a particular plan are not concerned with a particular variable, the value for that variable on the plan file will be a zero. Alternatively, it may be a disproportionately high figure. For example, co-insurance percentage may read as a zero. Maximum days supply may read as 1000.

The programs validate patient eligibility, eligibility of prescribed medication and quantity, adjust quantity, show lapsed cards, cost, pharmacist's charge, tapes, co-pay or percentage deduction are covered. "Reasonable charge" plans are accommodated, as are the rare cases of capitation. One standard claim form is used for the print-out. The computer prints the insurer's name on this form, and numbers the form. It then fills in the complete form.

The system automatically processes all plans which use one of the following options:

1) standard-wholesale cost

2) one of two lists of negotiated costs

3) one list of maximum allowance costs

4) any combination of the above options

5) "reasonable price" plans, and

6) "standard retail price" plans.

The system will automatically process any insurance plan which does not meet these requirements, if the accepted product cost is calculated off-line, and keyed in with the input data.

Insurance Billing

Each claim form is treated as an invoice. An accounts receivable file is set up. Once a week each insurer is sent a statement. A simple standard A/R-billing system is used.

It should be emphasized that the system covers only pharmaceutical products. Prosthetic appliances or other apparatus must be validated and calculated manually. A special routine allows for patient and "lapsed" validation in these cases, for print-out of claim form, and for insurance company billing and A/R.

Maintenance of Prescription Records and Files

These records output on the microfilm system. Within a few seconds, a print-out of any repeat prescription is available. This prescription is then entered as a new prescription, but the repeat prescription routine code is used.

Print-Out of Requisite Reports or Records

Reports are formated according to State, Provincial or Federal requirements. During Rx processing, data is moved from the prescription transaction file to storage on a report transaction file.

Each night, after the dispensary has closed, reports and records of the day's transactions are printed.

Calculation of Retail C.O.D. Price

The retail C.O.D. price is calculated on the basis of the true costs of prescription filling in any given dispensary. To assign a given fee to each prescription is not practical in the present price-competitive situation. To discount without a rigid accounting control is like Russian Roulette; will there be a profit at the end of the year or not?

The "TRIPS" system requires that figures for eight variables be entered each month. From these figures, assignable overhead, assignable purchases and a cost-multiplier are calculated, as are overhead and sales ratios. Assignable resource costs are calculated. Net profit complements are used to assure a margin of profit.

The fee concept is modified in a systematic way to assign a direct labor cost to each prescription, but to assign overhead costs which vary with actual cost of ingredients. The same net percentage profit is assured on each prescription.

The final formula (of a series of 4) reads as follows:

$$\text{C.O.D. price} = (0.11 + (\text{COST}(1+\text{CM}) \text{ X } \frac{\text{SL}}{\text{ST}} \text{ X } \frac{\text{OT}}{\text{OL}})^2 +$$

$$(\text{ARC} \text{ X } \frac{\text{LT}}{\text{TY}} \text{ X } \frac{\text{ETY}}{\text{ELY}})^2 \quad (1 + \frac{\text{GP}}{\text{GC}})$$

The four ratios in the equation could be replaced by rate-of-change-factors, to give a continuously adjusted price. However, this would cause too great a fluctuation in prices, as it would make the system responsive to daily fluctuations in volume. If ratio entries are made every 30 to 60 days, a net profit, close to that which is desired, can be assured without a great fluctuation in price. As a dispensary's volume increases, prices automatically are lowered every thirty days. The reverse is also true.

To complete the pricing function, provision is made for the eighty-odd products which are used as loss-leaders. Both the calculated C.O.D. price _and_ the price arrived at by multiplying cost by 1.666 are displayed. The pharmacist can key in either of the two suggested prices, or a third of his choosing.

If he chooses any other price than the calculated C.O.D. price, a plus or minus entry is made to an accumulated total in storage. At the regular 30 to 60 day price adjustment, the ± accumulated total, as well as the previous ± accumulated total, enter into the calculation of the new GP/GC ratio, to assure a leveling out of profits and losses.

Manual Packaging System

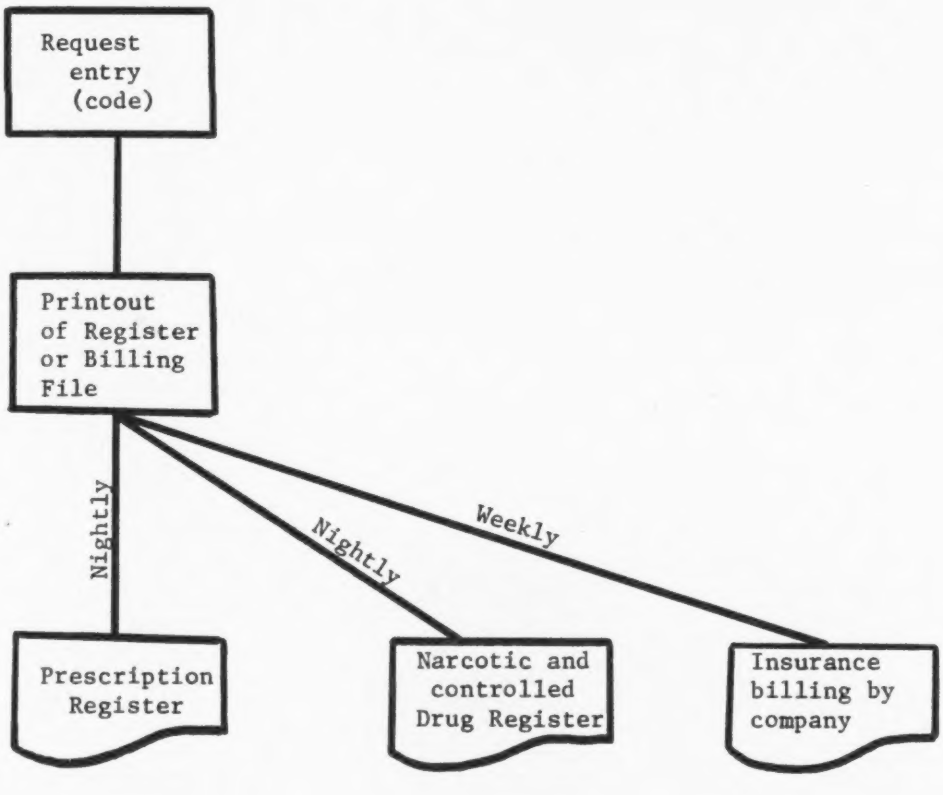
In effect, the manual packaging system is the application of manufacturing techniques and good warehousing practices to a dispensary. A volume of at least 500 prescriptions a day is required. The use of electric pill-counters, and liquid dispensers, allow for prepackaging of fast-moving sizes of fast-moving drugs.

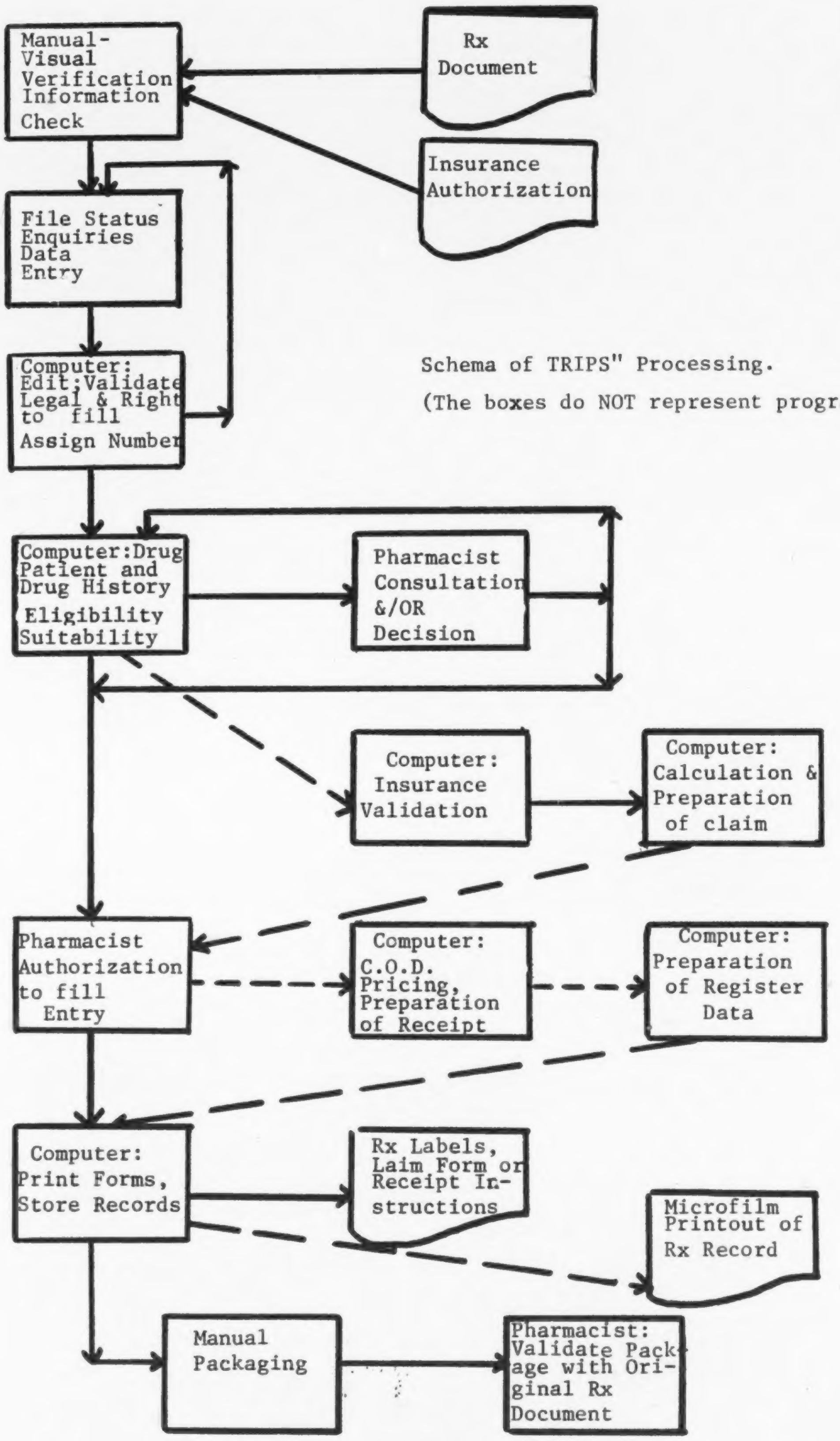
From computer print-out to final checking of the completed package, the prescription moves from station to station. The stations are modular in nature, each for a specific function. As in a good warehouse-shipping operation, the men stay put, only the order moves.

In a high vilume operation, (1,000 per day) the use of a fast conveyer belt and intercom are desirable.

A seven-module (station) dispensary has been designed to show the theoretical advantages of a rationally-planned dispensary.

Schema of report or register steps


Request
entry
(code)
Printout
of Register
or Billing
File
Nightly
Nightly
Weekly
Prescription
Register
Narcotic and
controlled
Drug Register
Insurance
billing by
company


Manual-
Visual
Verification
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Check
Rx
Document
Insurance
Authorization
File Status
Enquiries
Data
Entry
Computer:
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Legal & Right
to fill
Assign Number
Computer:Drug
Patient and
Drug History
Eligibility
Suitability
Pharmacist
Consultation
&/OR
Decision
Computer:
Insurance
Validation
Computer:
Calculation &
Preparation
of claim
Pharmacist
Authorization
to fill
Entry
Computer:
C.O.D.
Pricing,
Preparation
of Receipt
Computer:
Preparation
of Register
Data
Computer:
Print Forms,
Store Records
Rx Labels,
Laim Form or
Receipt Instructions
Microfilm
Printout of
Rx Record
Manual
Packaging
Pharmacist:
Validate Package with Original Rx
Document

Schema of TRIPS" Processing.

(The boxes do NOT represent programs.)

A UNIQUE METHOD FOR PHARMACY REIMBURSEMENT UNDER THE MEDICAID PROGRAM

Frank F. Yarborough*

Considerable attention has been given to many aspects of third party payments. Payment for services to pharmacists usually involves a fee for services for each prescription dispensed. Experience with this method has not proven entirely satisfactory either to the pharmacist or to the fiscal agent. In particular, this method of payment does not offer any incentive for controlling utilization.

Payment of a fee for each different drug dispensed during a calendar month offers an interesting possibility. Without the incentive for dispensing a prescription, more attention can be given to ascertaining whether or not the prescription should be refilled through communication with the patient and the physician.

The North Carolina Department of Social Services studied approximately 90,000 pharmacy claims including approximately 300,000 prescriptions and found a monthly refill rate of about 20 per cent. We proposed increasing the fee to $2.25, approximately a 29 per cent increase, to pay for the necessary refills and to encourage the pharmacist to give adequate consideration to the question of refill necessity.

This plan proposes paying the pharmacist the cost of drug dispensed plus a $2.25 dispensing fee the first time a drug is dispensed during a calendar month. After this, the pharmacist would receive only the cost of drug for any additional occasion that the same drug was dispensed during the same calendar month.

This proposal has the following advantages:

1. Program expenditures would be reduced by controlling overutilization and encouraging the pharmacist to dispense 30-day supplies of maintenance medications instead of smaller quantities.

2. Provider abuses from prescription - splitting and unnecessary refills would be controlled due to the absence of the profit motive.

3. Patient care would be enhanced by encouraging pharmacist-physician and pharmacist-patient communication.

This proposal has been reviewed by the Executive Committee and the Public Health and Welfare Committee of the North Carolina Pharmaceutical Association and has received their approval and endorsement.

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*Pharmacy Consultant to the North Carolina Department of Social Services

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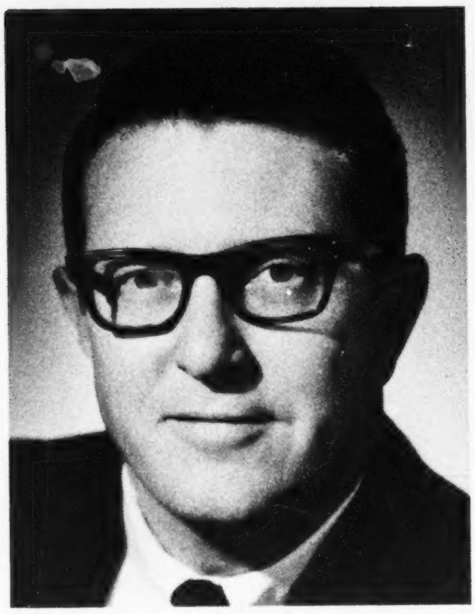

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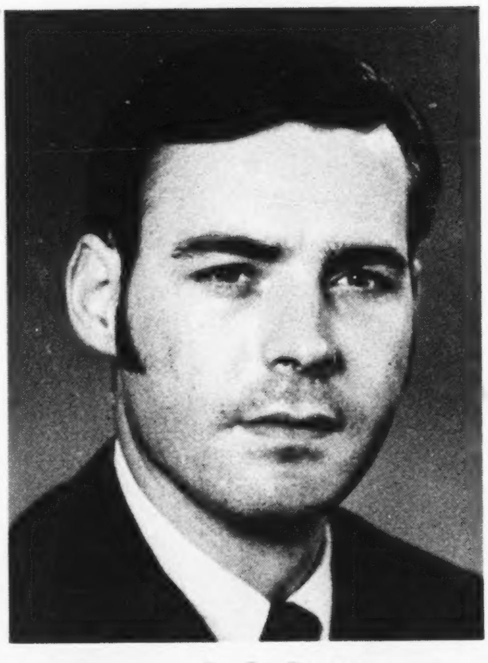

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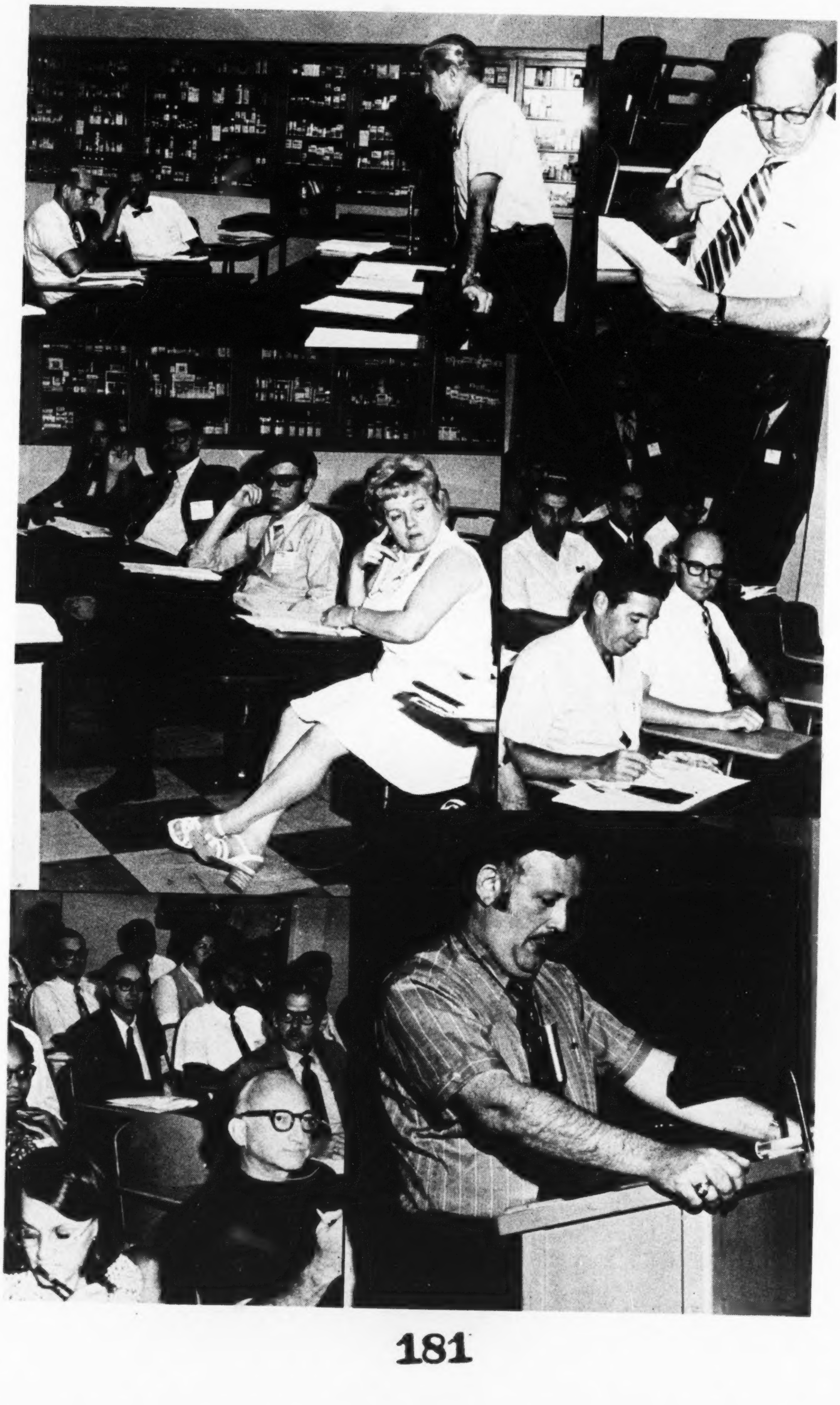

V. APPENDIX

1. POST-CONFERENCE QUESTIONNAIRE

REPORT ON POST-CONFERENCE QUESTIONNAIRE

The post-conference questionnaire was mailed to 115 persons (the University of North Carolina personnel, one-day attendees and sponsoring committee were not queried.)

The questions were framed so as to elicit an unstructured response; the intent being to allow wide latitude to all who replied. As a result; many persons made several points in response to each. For example, one listed seven reasons why the conference was useful; another listed four areas of failures.

Question 3, as to future steps to be taken, and question 4, additional suggestions, seemed to merge.

Question #1: "The Conference was useful in that..."

Those who replied agreed the conference was worthwhile. All said the meeting was useful, a few called it an "eye-opener"; others saw it as the first-time open meeting of many diverse groups concerned with this subject; or as a means of focusing attention on both opportunities and problems. One commented that the sessions "surfaced work that is going on and inter-related programs that are not mutually exclusive, e.g., government and third party reimbursements."

Question #2: "The Conference failed to..."

Criticisms were made chiefly in three areas as follows:

(a) The structure of the workshops - 13%
(b) Inadequate representation at the meeting of pharmacists, physicians, other health professions or negative-opinion holders - 24%
(c) The fact the conference did not produce concrete results in the form of system design, costs, and consideration of practicalities - 24%

However, 33% either did not reply to Question #2 or stated they had no negative reactions, or reversed the statement to make a compliment.

NOTE:

(a) Each workshop was organized independently by each panel. Papers were presented in some cases, which limited time for audience participation.
(b) There were at least 52 pharmacists and 6 physicians present. However, active community retail pharmacists were largely confined to panel members.
(c) Several persons felt the conference should have focused on system concepts in much greater detail than was programmed.

Question #3: "As to the future, I believe the following steps should be taken:..."

The prevailing response was that follow-up actions should be undertaken; in many cases rapid follow-through was urged. More than half the replies contained two to five suggestions. This fact affects the percentages recorded below.

The responses can be grouped roughly as follows: Those calling for follow-up meetings of various kinds, 42%; and those suggesting studies, surveys, planning activities, and pilot system trials, 80%. A third type of response, 22%, suggested programs of orientation and publicity, and fund seeking.

Suggestions for future meetings included one for this winter and several suggested an annual meeting to facilitate exchange of information and help keep up with the state of the art. Others suggested a meeting when a system developmental plan is ready, or when solutions appear for legal and political questions (as confidentiality of data). A few suggested specialized groups such as a meeting of pharmacists alone, of the scientific community only, or of system operators, and pharmacists to explore details.

The planning suggestions revolved around feasibility studies, establishment of research requirements, preparation of comprehensive system development plans, and establishment of pilot or model system operations.

Question #4: "I would further suggest the following:..."

Although more than a third did not respond to this question, those who did for the most part dealt with the following aspects, including conferences. One suggested limiting each workshop to ten to fifteen people. Others dealt with standardization suggestions; limitations on modules to be tested; hardware/software needs; data sources; confidentiality; physician/pharmacist/patient relationships. One urged, "put the responsibility where it belongs -- on the patient" in planning a system.

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Mr. David Ray	Western Carolina Center Morganton, N.C.
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3. COMMUNICATIONS

THE ASHP NATIONAL DRUG
INFORMATION SERVICE CENTER

Dear Dean Hager:

Enclosed is a copy of a letter and some additional materials which I have sent to Col. Aines. Col. Aines made reference to the ASHP proposal for a National Drug Information Service Center in his speech at the Computer Conference on July 20. His reference, however, was incomplete since he mentioned only that the proposal was made but had not come to fruition. He further mentioned that the Society proposed a drug code but did not indicate that the code has been developed and is in use in nearly 50 hospitals for many of the purposes discussed at the Conference.

As I felt it inappropriate to respond publicly to Col. Aines at the banquet, I spoke to him privately and asked if I might send him some descriptive materials regarding the matters he made reference to in his address. Much has transpired since the time referred to by Col. Aines and the Society has not been idle. In order that Conference participants and other interested parties may have a more complete picture therefore, I am requesting that my letter to Col. Aines and his reply to me be made a part of the official Conference proceedings. We look forward to your favorable response.

Very truly yours,

Mary Jo Reilly, Assistant Director
Bureau of Communication & Publication
Services, American Society of Hospital Pharmacists

. . . .

Col. Andrew A. Aines
National Science Foundation
1800 G Street, N.W.
Washington, D. C.

Dear Col. Aines:

As I indicated to you following your banquet address in Chapel Hill, North Carolina before the Computer Conference sponsored by the University of North Carolina, I am sending you some materials describing the activities of the American Society of Hospital Pharmacists relative to our proposed network of hospital-based drug information centers. Since you mentioned the Society's proposal in your speech, you might find the following synopsis of our proposal for a National Drug Information Service Center of interest.

Encouraged by the interest and enthusiasm for hospital-pharmacy based drug information services demonstrated by pharmacists, physicians, administrators and government representatives, the American Society of Hospital Pharmacists, in 1966, developed a proposal to establish a National Drug Information Service Center. This National Center would have been operated by the American Society of Hospital Pharmacists under the guidance of an advisory council and with the cooperation of the National Library of Medicine. The objective of the proposal was to provide service and information to the biomedical community through an inter-related network of local and regional drug information centers located in teaching hospitals and to coordinate the activities of these centers so as to provide for a two-way flow of drug information and to conduct research on drug usage. These drug information centers were to be established in selected institutions primarily but not necessarily from among 227 teaching hospitals of the United States having a major medical school affiliation.

Through this service mechanism, the vast biomedical resources of the National Library of Medicine could be made available to hundreds of individual physicians and allied personnel in teaching hospitals for the benefit of thousands of patients. Coordinated through the pharmacy and therapeutics committee of the medical staff, this service would have been provided by pharmacists as a formalization and extension of their traditional role, taking advantage of their strong educational background in the physical and biological sciences, their experience in giving drug information, and the centralization of drugs and drug information in the pharmacy departments of hospitals.

This service would have established a mechanism whereby hospital medical staffs could contribute their clinical experience and information to the pool of biomedical knowledge of the National Library of Medicine. The proposal also provided for the creation of traineeships to help unify the methods of operation of the drug information centers and to help to assure the future manpower needed to operate them.

The ASHP National Drug Information Service Center was to be located where its staff could work closely with the staff of the National Library of Medicine so as to utilize to the utmost the literature stores of the Library and to transfer information collected by the Center to the Library.

A seven-year program was called for in the proposal resulting in the creation of the ASHP National Drug Information Service Center and fifty drug information centers located in hospitals across the nation. The individual drug information centers would become operative on a staggered basis in order to provide for orderly implementation of the total program by staff of the ASHP National Drug Information Service Center. The individual drug information centers would be an integral part of the hospital's pharmacy department and would be organizationally related to the medical staff through the pharmacy and therapeutics committee.

Among the objectives of the proposed National Drug Information Service Center were these:

> --to maintain liaison with governmental and non-governmental organizations and associations which collect drug information with the objective of serving as a clearinghouse for released information drugs, forwarding all evaluated information to the central pool of drug information at the National Library of Medicine;
>
> --to conduct research on drug information; for example, to determine what are the most effective means for physicians to obtain it; to investigate the public's needs for drug information; to conduct sociological studies on drug information

and its uses; to study the effects of placing a drug information specialist in close daily contact with physicians; to study methods of improving the handling of drug information by members of the health team in hospitals; to look at the nationwide problems associated with the use of drugs and drug information; to improve the indexing of drug information by the National Library of Medicine so as to achieve more precise and rapid retrieval of information; to study patterns of drug therapy in hospitals; and to examine relationships between patients' diagnosis and drugs prescribed;

--to assist the medical staffs, working through pharmacy and therapeutics committees, to audit drug therapy in hospitals with the objective of promoting rational drug therapy and advancing teaching and research.

The grant proposal was under study by the American Society of Hospital Pharmacists for nearly two years and was reviewed informally by numerous individuals inside and outside government service. Formal submission for grant support was never made, however, on advice of representatives from the National Library of Medicine and the Public Health Service. During this same time period, numerous individual hospitals had submitted grant requests for establishing pharmacy-based drug information centers.

In the opinion of ASHP's advisors, submission of ASHP's request for funding of a National Drug Information Service Center and local centers on a matching fund basis would reduce the chances for individual submissions. In addition, the National Library of Medicine was just initiating its Drug Literature Program and was not able to provide facilities and staff for cooperation with the National Drug Information Service Center as proposed in ASHP's grant request.

In lieu of formal submission of its grant proposal, the American Society of Hospital Pharmacists turned its attention toward encouraging more individual hospitals to seek grant support for drug information services, to intensifying its own efforts in coordinating activities of existing drug information centers, and to conduct of additional continuing education programs in this area of professional practice. It was anticipated that at such time as individual hospitals had developed local drug information services, the proposal for a National Drug Information Service Center would again be reviewed with the intent of providing a coordination of local activities and a centralized drug information clearinghouse.

Part of the grant proposal called for development of a coding system for drug products which would provide a drug data bank for exchange of drug information utilizing computers and other electronic data processing equipment. The ASHP proceeded with this portion of the proposal and has in fact provided the Drug Products Information File as a magnetic tape leasing service since mid-1967. I am enclosing a copy of an article describing the Drug Products Information File which appeared in the July 16, 1971 issue of Hospitals, Journal of the American Hospital Association. The File is now in use in nearly 50 hospitals, including several groups of hospitals and by the State of Israel, Ministry of Health, as the drug data bank for an information system in all hospitals in Israel. In addition, the American Medical Association is a subscriber of the Drug Products Information File and a contract with the United States Pharmacopeial Convention is being finalized.

Since you showed considerable interest in the activities of the ASHP as evidenced by your mention of our proposal for a drug information network in your speech, I hope you will find these materials of interest. I feel, however, that your speech reference was incomplete and may have left the impression that the Society's activities in regard to the network and a drug code ended in 1964.

For this reason, I am asking Dean Hager and Mr. Olejar to include this letter as well as your reply to me in the official proceedings of the Conference. Further, our staff would be pleased to discuss the network proposal with you to obtain your reaction and your guidance as to whether it might be appropriate to submit a somewhat modified grant request to some government agency at this time.

We appreciate your interest in the activities of the American Society of Hospital Pharmacists and we look forward to receiving your reply.

Very truly yours,

Mary Jo Reilly

. . . .

August 26, 1971

Dr. Mary Jo Reilly
Assistant Director
Bureau of Communication & Publication Services
American Society of Hospital Pharmacists
4630 Montgomery Avenue
Washington, D.C. 20014

Dear Dr. Reilly:

Your letter of August 4, 1971 is deeply appreciated. You are quite correct in pointing out that some of those who heard my Chapel Hill speech may have been left with the impression that ASHP's activities in the network and drug code field have been dormant since 1964. I heartily approve the inclusion of your letter describing the continuing ASHP efforts in the official proceedings.

In regard to your network proposal, I hesitate to advise you during this period when curtailed Federal agency support makes new starts difficult. However, I would like to suggest that you discuss the situation afresh with Dr. Martin Cummings, Director, NIM. He is in the best position to give you sound advice.

Sincerely yours,

Andrew Aines
Senior Staff Associate

September 2, 1971

Mr. Paul D. Olejar

Dear Paul:

Thank you for your letter of August 10 and for the favorable decision you and Dean Hager have made regarding inclusion in the proceedings of your computer conference of my letter to Colonel Aines and his reply. Enclosed for your use is a copy of Colonel Aines' reply (dated August 26) to my letter of August 4, a copy of which you have already received.

In response to your request, I am also enclosing some additional descriptive materials on the Drug Products Information File, including a tape layout, glossary, description of the coding system and comparison with the National Drug Code. The paper on the potential of the computer in hospital pharmacy might provide you with some good background material on the thinking of the ASHP in this important area.

There are now about 50 hospitals utilizing DPIF, including The Latter-day Saints Church Hospital System, a group of hospitals operated by The Sisters of St. Francis headquartered in Beech Grove, Indiana and a group operated by The Sisters of Charity of Cincinnati. In addition, The American Medical Association is a subscriber and a contract with The United States Pharmacopeial Convention is in the final state of development. The 15 hospitals of the State of Israel will eventually utilize the File under an existing contract with the Ministry of Health which calls for development and implementation of programs in three hospitals before expanding to the additional twelve hospitals. Under the contract with the Ministry of Health of the State of Israel, our Israeli colleagues will input into DPIF European drugs and code numbers in the same format as those now in the File and will send us that information. In this manner, DPIF will have the capability of expanding to include European drug products as well as American ones. A similar arrangement has been made with our Canadian subscriber and we can also expand to include Canadian drug products.

The DPIF user closest to you is the University of Alabama Medical Center in Birmingham. You might contact Dr. Emmanuel Mesel for information on applications at the Medical Center. . . .

We appreciate your interest in the services and activities of the ASHP and hope you will call on us if we can be of further assistance.

Very truly yours,

Mary Jo Reilly, Assistant Director
Bureau of Communication & Publication Services